OFFICE OF DEVICE EVALUATION
AND
OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY

ANNUAL REPORT

FISCAL YEAR 2003

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health

OFFICE OF DEVICE EVALUATION
AND
OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY

ANNUAL REPORT

FISCAL YEAR 2003

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health

Acknowledgements

Thanks to the following organizations for their invaluable assistance in preparing this report:

ODE Program Operations Staff
ODE Review Divisions
ODE Program Management Office
OIVD Staff Offices
OSM Division of Planning, Analysis and Finance
OSM Division of Information Technology Management

Carl T. DeMarco, Project Director
Cathy Hobbs, Editor
MaryAnn Gornick, Production Specialist

TABLE OF CONTENTS

Table of Contents

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

PREFACE

Dear Reader:

Fiscal Year 2003 was an exciting year for ODE. One might assume that with the creation of the new Office of In Vitro Diagnostic Device Evaluation and Safety, that things would have gotten simpler and easier for those of left behind in ODE. That assumption would be very wrong. You will see many references specific to OIVD in this report including a wonderful introduction by my colleague and friend Dr. Gutman. You will also see that many of our activities and reports remain closely intertwined.

This was the year when MDUFMA became a reality and many individuals were asked to participate in implementation of all its many facets. This was a year, when, for the first time in almost a decade, we experienced significant growth in our most precious resource adding more than 70 professionals from a broad range of scientific disciplines including engineers, scientists and physicians. Additional expertise was added through expanded use of contracts, interns and other innovative methods of bringing the right knowledge to the right problem at the right time.

This was a year when CDRH reaffirmed its commitment to training and professional development for our new employees as well as those of us "seasoned veterans." Participation of approximately 95% of ODE staff in such activities demonstrates our ongoing determination to enhance the knowledge and skills needed to evaluate the cutting edge technology of today and tomorrow.

Speaking of innovative technology, this was a year that saw the introduction of the first drug-eluting stent, the first stair-climbing wheelchair, the first integrated glucose monitor and pump, and many other technological wonders that will help people lead longer and better lives. We recognize that there many more such products in the pipeline, and that the challenges of accomplishing our mission to evaluate their safety and effectiveness in a thorough and efficient manner will only increase. ODE, working with our colleagues throughout the Center, FDA, and our many sources of external expertise, will be ready to meet those challenges.

Daniel G. Schultz, M.D.
Director, Office of Device Evaluation

Philip J. Phillips, Deputy Director
Science and Regulatory Policy

Donna-Bea Tillman, Ph.D.
Deputy Director, Technology and Review Policy

Carl T. DeMarco, J.D.
Integrity Officer

Nancy J. Pluhowski
Advisory Panel Coordinator

Nancy C. Brogdon
Reproductive, Abdominal, and Radiological Devices

A. Ralph Rosenthal, M.D.
Ophthalmic and ENT Devices

Chiu Lin, Ph.D.
Anesthesiology, General Hospital, Infection Control and Dental Devices

Celia Witten, Ph.D., M.D.
General, Restorative and Neurological Devices

Bram Zuckerman, M.D.
Cardiovascular Devices

Kathyrn K. Appler
Program Management Office

Robert Gatling
Program Operations Staff

PREFACE

Dear Reader:

Welcome to the Office of In Vitro Diagnostic Device Evaluation and Safety's FY 2003 Annual Report. We at OIVD live in times of extensive change in our regulatory program. Following the central tenant in the CDRH strategic plan to regulate using the Total Product Life Cycle (TPLC) we have combined three key regulatory programs for IVDs (premarket review, compliance, and postmarket safety monitoring) into a single geographic unit. This allows all IVD activity to spring from a common consolidated technical and regulatory base.

During the past year we have created a website to serve the needs of the IVD community. We have standardized IVD review processes and began posting our reviews on this web page. This allows for improved quality control and transparency in our premarket work.

Finally, we have taken important steps to develop a more coordinated patient safety program that leads to rapid identification and resolution of product defects and problems. This program consists of several components: (1) review of MDR reports by scientific reviewers involved in the review of the products being reported, (2) the LabSun pilot (an expansion of the successful MedSun program but focused on clinical laboratories), and (3) active listening and follow-up of issues from all sources (listservs, professional meetings, trade complaints, the internet, and professional contacts) that warrant FDA evaluation. Collectively, these efforts have led to the identification and resolution of a number of device problems of public health significance.

OIVD management and staff look forward to working with all our stakeholders to develop ways to improve our performance in protecting and promoting public health in a timely, fair, and transparent manner clearly grounded in good science.

Steve Gutman, M.D.
Director, Office of In Vitro Diagnostic Device Evaluation and Safety

Donald St. Pierre
Deputy Director
New Device Evaluation

James Woods
Deputy Director
Patient Safety and Product Quality

Sousan S. Altaie, Ph.D.
Scientific Policy Advisor

Sally Hojvat, Ph.D.
Microbiology Devices

Jean Cooper, D.V.M.
Chemistry and Toxicology Devices

Joseph Hackett, Ph.D.
Immunology and Hematology Devices

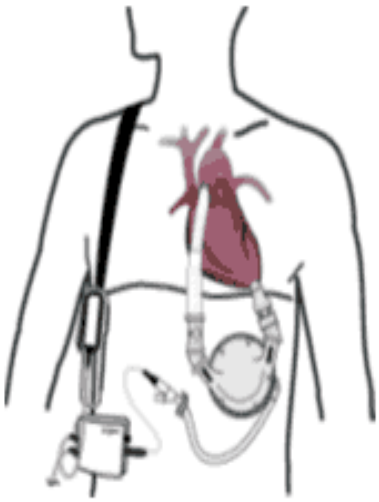
Part 1 – Advances in Patient Care

Last year the Office of Device Evaluation (ODE) and the Office In Vitro Diagnostic Device Evaluation and Safety (OIVD) approved and cleared thousands of devices used to diagnose and treat a wide variety of medical conditions. Below we highlight several new medical devices and devices with new indications approved or cleared during this past fiscal year that we believe will have a particular impact on patient care.

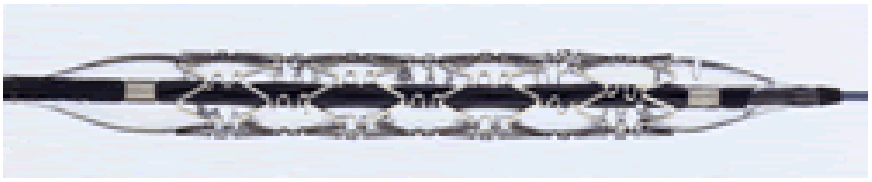
For a complete listing of newly approved devices, please see Part 2 – INDUSTRY INFORMATION under "Original PMA/HDE Approvals for Fiscal Year 2003." The Premarket Approval Application (PMA) approval website describing recently approved devices with patient information is available at http://www.fda.gov/cdrh/consumer/mda/index.html.

Office of Device Evaluation

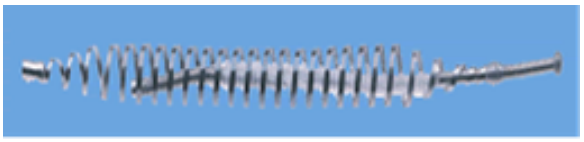
LEFT VENTRICULAR ASSIST DEVICE (LVAD) – HeartMate® SNAP-VE LVAS (Sutures Not Applied-Vented Electric Left Ventricular Assist System) by Thoratec Corporation is the first LVAD approved for long term implant. It was originally approved for use as a bridge to cardiac transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular failure. It is now also approved for use in patients who are not eligible for cardiac transplantation with New York Heart Association Class IV end stage left ventricular failure who have received optimal medical therapy for at least 60 of the last 90 days, and who have a life expectancy of less than two years. The device system is approved for use both inside and outside of the hospital.



DRUG-ELUTING STENT – CYPHER™ Sirolimus-eluting Coronary Stent by Cordis Corporation is the first drug-eluting stent for angioplasty procedures to open clogged coronary arteries. The device is an expandable, slotted, stainless steel tube, with a drug (sirolimus) contained within a thin polymer coating on its surfaces. The Stent is mounted over a balloon on the end of a long thin flexible tube called a "delivery catheter" (RAPTOR™ Over- the-Wire Delivery System or RAPTORRAIL® Rapid Exchange Delivery System). This new stent slowly releases a drug, and has been shown in clinical studies to significantly reduce the rate of re-blockage that occurs with existing stents. The device should not be used in patients: who cannot take aspirin or blood-thinning medicine, who have an allergy to the drug sirolimus, its derivatives or the polymers used to coat the stent, or who have a blockage in the coronary artery that will not allow complete inflation of the balloon.

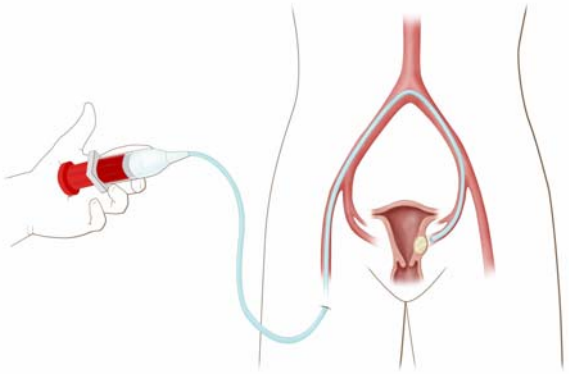


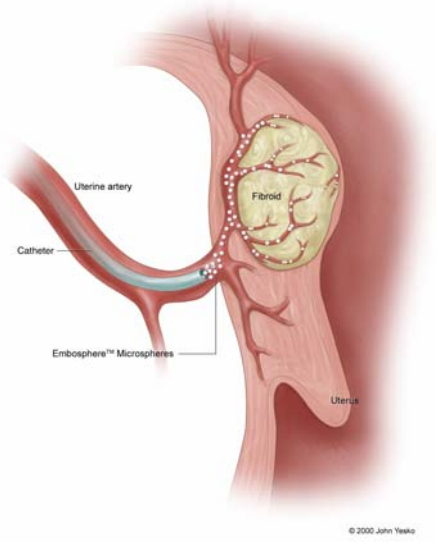
ADVANCES IN PATIENT CARE



STERILIZATION PROCEDURE FOR WOMEN – The Essure™ System by Conceptus, Inc. is a new method of permanent birth control (sterilization) for women. Unlike other sterilization procedures for women, this system does not require incisions or general anesthesia. Instead, a doctor implants small metal coils in a woman's fallopian tubes by threading them through the vagina and uterus using a specialized delivery catheter. After the catheter is removed, the coils remain in place permanently. Over time, scar tissue forms around the implanted coils and blocks the fallopian tubes, preventing sperm from fertilizing a woman's eggs. Initial one and two-year data from clinical studies showed no pregnancies at the time of approval. Longer term data will be available over time with postmarket follow-up of these patients.

FIBROID EMBOLIZATION – Uterine Fibroid Embolization by Biophere Medical, Inc. is the first 510(k) cleared for Uterine Fibroid Embolization (UFE). It is indicated to treat symptomatic fibroids (noncancerous tumors). A radiologist makes a small nick in the skin (less than one-quarter inch) and inserts a thin tube (catheter) into the main artery of the thigh (femoral artery). Using X-ray imaging, the radiologist guides the catheter through the femoral artery into the uterine artery. Tiny spheres or particles made of plastic or sponge material the size of grains of sand are pumped through the catheter into the uterine artery on one side of the body, where they block the blood supply to the fibroids. The procedure is then repeated on the other side of the body so the blood supply is blocked in both the right and left uterine arteries. With decreased blood supply, part of the fibroid tissue dies. The overall effect is shrinking of the fibroid.





LIMB SALVAGE SYSTEM – Children who require replacement of their knee joints often lose the ability for growth in the affected limb. This necessitates several surgeries throughout childhood and adolescence to expand the child's prosthesis as the child grows to maintain limb length equality.

ADVANCES IN PATIENT CARE

The REPIPHYSIS™ Limb Salvage System, manufactured by Wright Medical Technology, Inc., is an artificial knee joint with a unique femoral component that can be expanded without surgical intervention. The device utilizes a coil that fits around the patient's leg that produces an electromagnetic field (EMF). The EMF induces an electrical current and subsequent heating of an internal wire. The generated heat softens a polymer locking ring, allowing a slow expansion of an internal compressed spring. The spring expansion pushes the spring housing and femoral housing apart, thus increasing the overall length of the implant.

DEEP BRAIN STIMULATOR – Medtronic Activa® Dystonia Therapy is a totally implanted brain stimulator to treat long-term primary dystonia (abnormal contraction of muscles at rest) that is not responsive to drug therapy.

An implanted pulse generator (IPG) is connected with a lead (insulated wire) extension, to another lead with four electrodes. The electrodes are in contact with a specific structural area within the brain. The IPG is implanted under the skin of either the abdomen or under the collar bone, and sends programmable electrical stimulation pulses to the electrodes that were implanted in the brain. Two IPG device systems may be implanted, so that both sides of the brain can be stimulated to relieve symptoms on both sides of the body.

It may improve some symptoms associated with primary dystonia. However, individual results vary and the specific benefit for an individual cannot be predicted.

STAIR CLIMBING WHEELCHAIR - The INDEPENDENCE™ iBOT™ 3000 Mobility System by Independence Technology, L.L.C. is a new indoor/outdoor power mobility device for use by people with mobility impairments and the use of at least one upper extremity. It provides mobility on smooth surfaces and inclines at home and in the community; movement over obstacles, uneven terrain, curbs, grass, gravel, and other soft surfaces; mobility in a seated position at an elevated height; ascent or descent of stairs with or without assistance; and transport of the unoccupied wheelchair. Because of its unique balancing mechanism, the device remains stable and the seat stays level under most conditions. The iBOT™ is available by prescription only, from specially trained health professionals.

ADVANCES IN PATIENT CARE

EXTERNAL INSULIN PUMP – The Medtronic MiniMed Paradigm Model 512 Insulin Pump and BD Paradigm Link Glucose Monitor by Minimed, Inc. is an ambulatory, battery operated, rate-programmable microinfusion pump. The Model 512 Insulin Pump is indicated for the continuous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin. The BD Paradigm Link Blood Glucose Monitor is an in-vitro diagnostic device intended to be used for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, by people with diabetes mellitus in the home, as an aid to monitor the effectiveness of diabetes control. When used together, the glucose monitor can automatically telemeter glucose values to the insulin pump using radio frequency communication. The glucose monitor can also serve as a radiofrequency interface to allow communication between the insulin pump and a personal computer running the appropriate Medtronic MiniMed communications software.

Office of In Vitro Diagnostic Device Evaluation and Safety

A1C NOW FOR HOME USE – December 13, 2002, FDA cleared the A1C Now for Home Use device. This device provides a quantitative measurement of the percent of glycated hemoglobin levels in capillary blood samples. This test is used at home by patients who have diabetes to monitor long term glycemic control.

BAYER ADVIA CENTAUR SERUM HER-2/NEU ASSAY – January 30, 2003, FDA cleared the Bayer Advia Centaur serum Her-2/neu assay used in the follow-up and monitoring of patients with metastatic breast cancer whose initial serum Her-2/neu level is greater than 15 ng/ml. Her-2/neu values should be used in conjunction with information available from clinical and other diagnostic procedures in the management of breast cancer. The clinical utility of the measurement of Her-2/neu in serum as a prognostic indicator for early recurrence and in the management of patients on immunotherapy has not been fully established.

INVASIVE FUNGAL INFECTION – May 16, 2003, FDA cleared The Platelia® Aspergillus EIA test, manufactured by Bio-Rad Laboratories. This is the first rapid laboratory test to detect *Aspergillus* galactomannan antigen in blood, as an indicator of invasive infection. The test will help doctors diagnose invasive *Aspergillus* infection, a life-threatening

invasive fungal infection that often occurs in leukemia patients, organ and bone marrow transplant patients, and patients whose immune systems are compromised by illness or chemotherapy, much sooner than current laboratory methods. Results are available in about three hours. By comparison, the standard culture method of testing for *Aspergillus* takes a minimum of four weeks before results are available. Earlier detection means earlier intervention with life-saving treatment for these critically ill patients.

WEST NILE VIRUS INFECTION – July 3, 2003, FDA cleared the West Nile Virus IgM Capture ELISA test, manufactured by PanBio, Limited. This is the first test for use as an aid in the clinical laboratory diagnosis of West Nile Virus infection. The test is intended for use in patients with clinical symptoms consistent with encephalitis. West Nile virus is a mosquito-borne flavivirus that until 1999 was found only in the Middle East, Eastern Europe and Africa. The disease first appeared in the United States in 1999 and in 2002 over 3300 cases were identified. Transmission to humans is primarily by mosquito. While the virus often presents as a mild infection that clears without further treatment, some patients develop severe infection resulting in severe neurological disease and even death. Antibodies for IgM can be seen within the first 1 to 8 days after onset of disease and can assist in the diagnosis of these patients. The disease is most prevalent during the mosquito season which is expected to begin in July and end in October. Over the past several years, the geographic range of the virus as well as the number of new infections has expanded and now covers most of the continental United States. This test will be of use in helping to diagnose this growing public health problem.

DIAGNOSIS OF CONGESTIVE HEART FAILURE – November 19, 2002, FDA cleared the Elecsys proBNP Immunoassay test. This test is a first-of-a-kind fully automated test for diagnosing congestive heart failure. The automation allows the laboratory to run a higher volume of samples, making the test more readily available to patients who need it. The Elecsys proBNP Immunoassay test is made by Roche Diagnostics, Inc., of Indianapolis, Indiana and is run on the Roche Diagnostics Elecsys Analyzers. The test detects the level of a peptide, NT-proBNP, which is secreted almost exclusively by the heart. An elevated level can indicate the presence of congestive heart failure. The higher the blood levels of proBNP, the more serious the condition. FDA cleared the first laboratory test for use as an aid in diagnosing congestive heart failure, the Biosite Diagnostics Triage BNP test in November 2000. The test can help doctors differentiate between congestive heart failure and other problems, such as lung disease. Early detection of congestive heart failure is important because, if detected early, it can often be managed with medication.

ADVANCES IN PATIENT CARE

RULING OUT HEART ATTACK – February 14, 2003, FDA cleared the Albumin Cobalt Binding Test (ACB Test). This test is a new first-of-a-kind blood test that measures Ischemia Modified Albumin (IMA). IMA helps in determining that a patient has NOT had a heart attack when he or she presents to an emergency room with severe chest pain. The ACB Test is manufactured by Ischemia Technologies Inc., of Arvada, Colorado. It uses human serum and detects IMA by measuring how much cobalt is bound to the blood protein albumin. The ACB Test works by detecting albumin levels. A cobalt solution is added to serum and the unbound cobalt is detected by a color indicator. In the serum of normal patients more cobalt is bound to albumin leaving less cobalt to be detected by the color indicator, and forms less color. In patients with non-normal albumin levels, less cobalt is bound to albumin, which leaves more free cobalt to react with the color indicator, forming more color. The ACB Test is used as an additional test with both electrocardiogram (ECG) and another chemical marker--Troponin. ACB is not intended for use as a stand alone heart attack test. A normal ACB Test with a normal ECG, and a normal Troponin, gives doctors more confidence that patients can go home because they did not have a heart attack.

MONITORING ASTHMA BETTER – April 30, 2003, FDA cleared the Nitric Oxide (NIOX) Test System. This test is a first of a kind, non-invasive test system to measure the concentration of nitric oxide in exhaled human breath. The test system helps make it easier for doctors to monitor a patient's asthma. The NIOX Test is manufactured by Aerocrine AB of Sweden. It combines equipment that detects nitric oxide and equipment that analyzes exhaled breath with a special computer system. To use the device, a patient places the mouthpiece over his or her mouth. The mouthpiece is connected to the equipment and the computer. Patient inhales nitric oxide-free air to total lung capacity, and then slowly exhales into the mouthpiece. The nitric oxide concentration is then displayed immediately on the computer screen. Doctors can use the device in their office to evaluate their patient's response to anti-inflammatory treatment.

PREDICTING CORONARY HEART DISEASE – July 18, 2003, FDA cleared the PLAC Test. This test is a first of a kind, laboratory blood test that will increase the ability of doctors to predict the risk of coronary heart disease (CHD). The PLAC test is manufactured by diaDexus, Inc. of San Francisco, California. The test works by measuring an enzyme called lipoprotein-associated phospholipase A2. This enzyme is made by a type of white blood cell called a macrophage. Macrophages make more of this enzyme and release it into the blood when a person has CHD. The test provides supportive information when used with clinical evaluation and other tools for patient

risk assessment. An elevated PLAC test result with an LDL-cholesterol less than 130 mg/dL gives doctors increased confidence that patients have 2 to 3 times the risk of CHD when compared with patients having lower PLAC test results.

FDA Consumer Websites

Publicly Available Device Databases

The Center for Devices and Radiological Health (CDRH) maintains a website with additional consumer information about medical devices at http://www.fda.gov/cdrh/consumer/product.html. This website appears in a searchable format for the public.

Consumer Information

The Division of Small Manufacturers, International and Consumer Assistance (DSMICA) also provides information to consumers regarding medical devices and radiation-emitting products to enhance users ability to avoid risk, achieve maximum benefit, and make informed decisions about the use of such products.

Website: http://www.fda.gov/cdrh/consumer/index.html
E-Mail: dsmica@cdrh.fda.gov
Phone: Toll Free 1-888-463-6332 or 301-827-3990 directly between the hours of 8:00 a.m. – 4:30 p.m. EST
Fax: 301-443-9535

Part 2 – Industry Information

ODE/OIVD review four major types of marketing applications: Premarket Notification (i.e., a 510(k) submission), Premarket Approval Application (PMA), Product Development Protocol (PDP), and Humanitarian Device Exemption (HDE). Devices cleared for marketing through the 510(k) process are too numerous to list here but can be found at http://www.fda.gov/cdrh/consumer/mda//.

During Fiscal Year 2003, no PDPs were completed, but ODE/OIVD approved 31 PMAs and 2 HDEs. These are listed below. We recommend turning to the PMA approval website, which is available at http://www.fda.gov/cdrh/consumer/mda//, for easy-to-understand one pagers for each PMA approved.

Original PMA/HDE Approvals for Fiscal Year 2003

		COMPANY	DEVICE
04-Nov-02	P020014	Conceptus, Inc.	Essure System (Contraceptive Tubal Occlusion Device)
06-Nov-02	P020004	W. L. Gore & Associates, Inc.	EXCLUDER™ Bifurcated Endoprosthesis
07-Nov-02	P020011	Gen-Probe, Inc.	Versant™ HCV RNA Qualitative Assay
27-Nov-02	P990069	EPMedSystems, Inc.	ALERT® System
12-Dec-02	P020008	Karl Storz Endoscopy-America, Inc.	Karl Storz Autofluorescence System
18-Dec-02	P020007	Medtronic, Inc.	Medtronic AVE Bridge™ Extra Support Over-the-Wire (OTW) Renal Stent System
23-Dec-02	P010055	Prostalund Operations AB	ProstaLund CoreTherm System Microwave Thermotherapy for BPH (Benign Prostatic Hyperplasia)
03-Jan-03	P020028	Phillips Medical Systems, Inc	Series 50 XMO Fetal/Maternal Monitor (Model M1350C) with Integrated Fetal Oxygen Monitoring (Fetal Oximeter)
24-Jan-03	P020027	Dade Behring, Inc.	Dimension FPSA Flex Reagent Cartridge and Dimension T/F PSA
03-Feb-03	P010001	Ceramtec AG	Ceramic Transcend Hip Articulation System
03-Feb-03	P000013	Howmedica Osteonics Corp.	Osteonics ABC System and Trident Ceramic System
14-Mar-03	P010065	E MED Future	Needle Zap™
28-Mar-03	P020022	Bayer Corp.	Bayer Versant™ HCV RNA 3.0 Assay
28-Mar-03	P020041	FemCap Incorporated	FemCap™ Barrier Contraceptive
15-Apr-03	H020007	Medtronic, Inc.	Medtronic Activa® Dystonia Therapy
17-Apr-03	P020045	CryoCath Technologies Inc.	7F Freezor® Cardiac Cryoablation Catheter and CCT.2 CryoConsole System
22-Apr-03	P020006	Enteric Medical Technologies, Inc.	Enteryx™ Procedure Kit

24-Apr-03	P020026	Cordis Corporation	CYPHER™ Sirolimus-eluting Coronary Stent on RAPTOR™ Over- the-Wire Delivery System or RAPTORRAIL® Rapid Exchange Delivery System
07-May-03	P020052	St. Jude Medical	Response™ CV Catheter System
14-May-03	P020024	AGA Medical Corporation	AMPLATZER® Duct Occluder and 180° Delivery System
23-May-03	P020018	Cook Incorporated	Zenith® AAA Endovascular Graft and H&L-B One-Shot Introduction System
06-Jun-03	P020002	Cytyc Corp.	ThinPrep™ Imaging System
11-Jun-03	P020037	Guidant Corp.	FX miniRAIL™ RX Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
07-Jul-03	P030027	Wright Medical Technology, Inc.	Ceramic Transcend Hip Articulation
07-Jul-03	H020004	Smith and Nephew Wound Management	Dermagraft®
16-Jul-03	P020047	Guidant Corporation	MULTI-LINK RX and OTW VISION™ Coronary Stent Systems
29-Jul-03	P020049	Hancock Jaffe Laboratories, Inc.	ProCol® Vascular Bioprosthesis
01-Aug-03	P020021	AXCAN Scandipharm, Inc.	Wizard X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser
12-Aug-03	P020036	Cordis Corporation	S.M.A.R.T.™ and S.M.A.R.T.™ Control™ Nitinol Stent System
13-Aug-03	P020033	Independence Technology, L.L.C.	INDEPENDENCE™ iBOT™ 3000 Mobility System
25-Aug-03	P020025	Boston Scientific	EP Technologies EPT-1000 XP™ RF Ablation System
23-Sep-03	P020031	Microsulis Medical, Ltd.	Microwave Endometrial Ablation System (Thermal Endometrial Ablation Device)
30-Sep-03	P020035	X-Site Medical, L.L.C.	X-PRESS™ 6 French Vascular Closure System

Significant Medical Device Approvals

The following devices were approved via PMAs, PMA Supplements, and HDEs or cleared via 510(k)s or classified via the Automatic Evaluation of Class III Designation process during FY 03. They represent significant medical breakthroughs because they are first-of-a-kind, e.g., they use a new technology or energy source, or they provide a major diagnostic or therapeutic advancement, such as reducing hospital stays, replacing the need for surgical intervention, reducing the time needed for a diagnostic determination, etc. The information for each device includes the trade name and/or classification name, firm, and date of approval or clearance.

- ODE PMA/HDE Approved Devices

Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGID)

NeedleZap™ by E MED Future (March 14, 2003)

Division of Cardiovascular Devices (DCD)

Thoratec HeartMate® SNAP-VE LVAS (Sutures Not Applied-Vented Electric Left Ventricular Assist System) by Thoratec Corporation (November 6, 2002)

CYPHER™ Sirolimus-eluting Coronary Stent on RAPTOR™ Over-the-Wire Delivery System; CYPHER™ Sirolimus-eluting Coronary Stent on RAPTORRAIL® Rapid Exchange Delivery System by Cordis Corporation (April 24, 2003)

Division of General, Restorative, and Neurological Devices (DGRND)

Ceramic Transcend Hip Articulation System by Ceramtec AG (February 3, 2003)

Osteonics ABC System and Trident Ceramic System by Howmedica Osteonics Corp. (February 3, 2003)

Medtronic Activa® Deep Brain Stimulation (DBS) System by Medtronic, Inc. (April 15, 2003)

INDEPENDENCE™ iBOT™ 3000 Mobility System by Independence Technology, L.L.C. (August 13, 2003)

Division of Ophthalmic and Ear, Nose, and Throat Devices (DOED)

LADARVision® 4000 Excimer Laser System by Alcon Laboratories, Inc. (October 18, 2002)

STAR S4 ActiveTrak™ Excimer Laser System and WaveScan WaveFront® System by VISX, Inc. (May 23, 2003)

Division of Reproductive, Abdominal and Radiological Devices (DRARD)

The Essure™ System by Conceptus, Inc. (November 4, 2002)

- OIVD PMA/HDE Approved Device

ThinPrep™ Imaging System by Cytye Corporation (June 6, 2003)

- ODE 510(k) Clearances or Automatic Evaluations of Class III Designation Devices

DDIGD

Reactive Skin Decontamination Lotion (RSDL) by O'Dell Engineering Ltd./E-Z-EM Canada Inc. (March 25, 2003)

DGRND

Repiphysis Limb Salvage System by Wright Medical Technology, Inc. (December 4, 2002)

TenoFix Tendon Repair System by Ortheon Medical Llc. (January 22, 2003)

DOED

TGDc-01 "PRA" Tonometer by Truvision Instruments (October 11, 2002)

MP-1 Micro Perimeter by Nidek Technologies (December 23, 2002)

DRARD

Embosphere Microspheres and Embogold Micropheres by Biosphere Medical, Inc. (November 22, 2002)

Contour Emboli Pva and Fastracker-325 Infusion Catheter by Boston Scientific Corp. (September 23, 2003)

- OIVD 510(k) Clearances or Automatic Evaluations of Class III Designation Devices

Group B Streptococcus Detection Assay by Infectio Diagnostic, Inc. (November 18, 2002)

QCS Her/2 Immunocontrols by OC Sciences (June 18, 2003)

ODE Guidance Documents

In FY 03, ODE and OIVD issued 3 Blue Book Guidance Memoranda and 28 other guidance documents, 22 final and 6 draft, which are listed below. Of the total, 7 are related to the implementation of MDUFMA. Of the 28, 12 are Special Controls guidance, 10 final and 3 draft. These guidance documents and other previously issued guidance documents are available on the World Wide Web (CDRH homepage:

http://www.fda.gov/cdrh) which provides easy access to the latest information and operating policies and procedures. They may also be obtained from the Division of Small Manufacturers International and Consumer Assistance (DSMICA, HFZ-200). To contact DSMICA, call 800-638-2041 or 301-443-6597; fax 301-443-8818; Email dsma@cdrh.fda.gov or write to DSMICA (HFZ-200, Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307.) Many guidance documents are also available through the CDRH Facts-On-Demand (faxback service at 800-899-0381 or 301-837-0111).

- ODE and OIVD Final Guidance Documents Adopted

ODE/OIVD

The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles: Final Guidance for FDA and Industry (October 4, 2002)

ODE/OIVD MDUFMA Guidance Documents Adopted

Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff (Update to K98-1). This guidance has been updated to reflect the change made by section 208 of MDUFMA (December 3, 2002)

Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products; Guidance for Industry and FDA (February 25, 2003)

Section 206 of the Medical Device User Fee and Modernization Act (MDUFMA) (New Section 502(f) of the Federal Food, Drug and Cosmetic Act) Electronic Labeling for Prescription Devices Intended for Use in Health Care Facilities (Blue Book Guidance Memorandum #G03-1, March 31, 2003)

Premarket Approval Application Filing Review - Guidance for Industry and FDA Staff (May 1, 2003)

Pediatric Expertise for Advisory Panels - Guidance for Industry and FDA Staff, (June 3, 2003)

Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices - Guidance for Industry and FDA Staff, (July 8, 2003)

Premarket Assessment of Pediatric Medical Devices - Draft Guidance for Industry and FDA Staff, (July 24, 2003)

- ODE Final Guidance Documents Adopted

ODE

Intercenter Consultative/Collaborative Review Process (Blue Book Guidance Memorandum #G02-1, October 3, 2002)

A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff (June 26, 2003)

DCD

Coronary and Peripheral Arterial Diagnostic Catheters - Guidance for Industry and FDA Staff (July 15, 2003)

DAGID

Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA (November 12, 2002)

Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCo2) and Oxygen (Pc02) Monitors; Guidance for Industry and FDA (December 13, 2002)

Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA (December 31, 2002)

Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA (April 22, 2003)

DGRND

Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA (January 16, 2003)

Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Guidance for Industry and FDA (February 11, 2003)

Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Final Guidance for Industry and FDA (June 2, 2003)

Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA (June 3, 2003; Draft Issued December 19, 2002)

DOED

Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA (November 7, 2002)

Guidance for Industry and FDA Staff Implantable Middle Ear Hearing Device (August 1, 2003)

DRARD

Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices – Guidance for Industry and FDA Staff (July 14, 2003)

Class 11 Special Controls Guidance Document: Breast Lesion Documentation System – Guidance for Industry and FDA Staff (July 28, 2003)

- OIVD Final Guidance Documents Adopted

Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA Staff (February 5, 2003)

Analyte Specific Reagents; Small Entity Compliance Guidance; Guidance for Industry (February 26, 2003)

510(k) Submissions for Coagulation Instruments - Guidance for Industry and FDA Staff (June 19, 2003)

Class II Special Controls Guidance Document: Breath Nitric Oxide Test System - Guidance for Industry and FDA Staff (July 7, 2003)

- ODE Draft Guidance Documents for Comment Purposes Only

Class II Special Controls Guidance Document: Processed Human Dura Mater; Draft Guidance for Industry and FDA (October 22, 2002)

Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm; Draft Guidance for Industry and FDA (December 13, 2002)

Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA (December 19, 2002; Final Issued on June 3, 2003)

Chemical Indicators Premarket Notification 510(k) Submissions; Draft Guidance for Industry and FDA (January 27, 2003)

Surgical Masks - Premarket Notification 510(k) Submissions; Draft Guidance for Industry and FDA (May 15, 2003)

- OIVD Draft Guidance Documents for Comment Purposes Only

Multiplex Tests for Heritable DNA Markers, Mutations and Expression Patterns; Draft Guidance for Industry and FDA Reviewers (February 27, 2003)

Part 3 – Key Performance Indices

ODE/OIVD are responsible for protecting the rights, safety and welfare of patients participating in clinical studies of significant risk medical device research and for evaluating the safety and effectiveness of medical devices before these devices enter the U.S. market place. Following are the details of ODE's and OIVD's review activities and performance for Fiscal Year 2003 (FY 03). Most of the data discussed below can be found in the tables below and in Part 7- OPERATIONAL STATISTICS. First, we present the major submissions received and completed. Next, we review the Premarket Approval Applications (PMAs) in terms of review time as well as volume. This same analysis is done for PMA supplements. The remainder of this part deals with Humanitarian Device Exemptions (HDEs), Investigational Device Exemptions (IDEs), and Premarket Notifications (510(k)s).

Resources

ODE ended FY 2003 with 338 employees. During the year, ODE lost 17 full-time employees (13 scientific reviewers, 2 medical officers, 1 clerical and 1 program analyst) through resignation, reassignment or retirement and added 72 new employees (34 scientific reviewers, 9 medical officers, 5 project managers, 1 clerical, 7 paid student interns, 12 non-paid student interns and/or contractors, and 4 joint hires with OSB (2), OST and OHIP).

OIVD ended FY 2003 with 71 employees. During the year, OIVD lost 4 full-time employees (4 scientific reviewers) through resignation, reassignment or retirement and added 17 new employees (10 scientific reviewers, 2 project managers, 1 consumer safety technician, 1 medical officer, and 3 managers (one of which is a medical officer).

Workload

During FY 03, ODE/OIVD received 9,872 major submissions compared to 10,323 major submissions in FY 02. [See Table 1 for a breakdown of major submissions received.]

Table 1. Major Submissions Received FY 93 – FY 03

TYPE OF SUBMISSION	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Original PMAs	40	43	39	44	66	48	64	67	71	49	54
PMA Supplements	395	372	499	415	409	517	557	546	641	645	669
Original IDEs	241	171	214	253	297	322	304	311	284	312	242
IDE Amendments	320	254	210	219	223	226	275	240	206	252	216
IDE Supplements	3,668	3,020	3,171	3,189	3,776	4,277	4,127	4,388	4,811	4,724	4,415
510(k)s	6,288	6,434	6,056	5,297	5,049	4,623	4,458	4,202	4,248	4,320	4,247
Original HDE	0	0	0	0	4	8	12	11	5	5	10
HDE Supplements	0	0	0	0	0	0	4	10	16	16	29
Total	**10,952**	**10,294**	**10,189**	**9,417**	**9,824**	**10,021**	**9,801**	**9,775**	**10,282**	**10,323**	**9,872**

On the decision side, ODE/OIVD completed the processing of 9,570 major submissions, compared to 10,238 major submissions in FY 02. [See Table 2 for major submissions completed.]

Table 2. Major Submissions Completed FY 93 - FY 03

TYPE OF SUBMISSION	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Original PMAs	24	26	27	43	48	40	36	42	53	41	31
PMA Supplements	354	385	435	462	401	421	440	474	442	533	494
Original IDEs	248	174	210	260	272	325	305	320	284	307	246
IDE Amendments	324	256	213	218	220	225	268	251	207	251	217
IDE Supplements	3,814	3,070	3,181	3,121	3,777	4,209	4,224	4,335	4,803	4,711	4,424
510(k)s	5,073	7,135	7,948	5,563	5,155	5,229	4,593	4,397	4,150	4,376	4,132
Original HDE	0	0	0	0	2	4	6	6	4	6	2
HDE Supplements	0	0	0	0	0	0	3	10	11	13	24
Total	**9,837**	**11,046**	**12,014**	**9,667**	**9,875**	**10,453**	**9,876**	**9,835**	**9,954**	**10,238**	**9,570**

Premarket Approval Applications (PMAs)

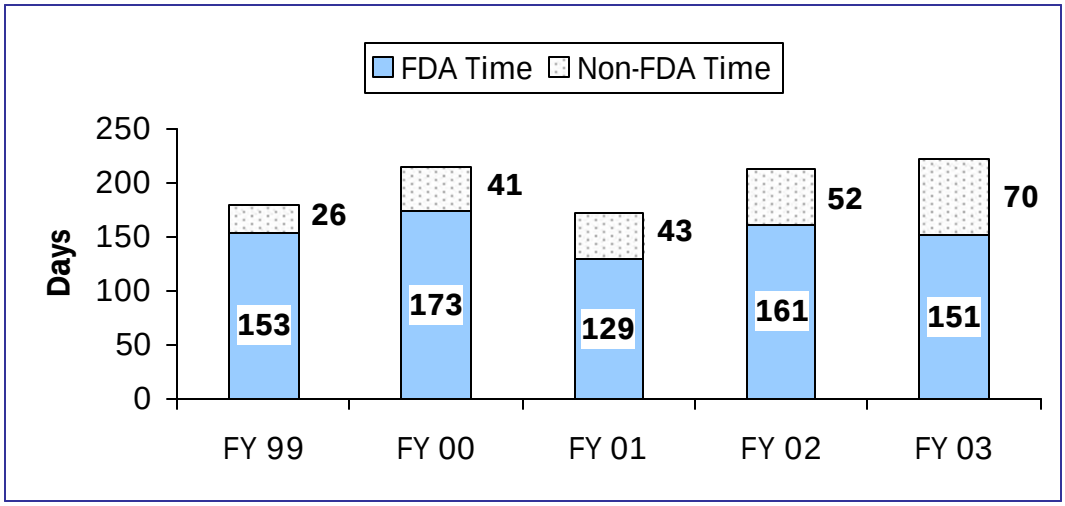
ODE/OIVD received 54 original PMAs (5 more than the number received in FY 02). The total number of PMAs in inventory (active and on hold) at the end of this fiscal year increased from 73 in FY 02 to 83. The number of active PMAs under review decreased at the end of FY 03 to 35 compared to 42 last year, and those on hold increased from 31 in FY 02 to 48 in FY 03.

The total number of PMA actions decreased from 237 to 198 actions. These actions included 54 filing decisions, 87 scientific review decisions, and 57 approval/approvable/not approvable decisions.

The 57 original PMA decisions comprised 31 approved PMAs, 16 approvable PMAs, and 10 not approvable PMAs. Of the 31 approvals, 5 were expedited PMAs. See Part 2 (INDUSTRY INFORMATION) for a complete list of PMA approvals.

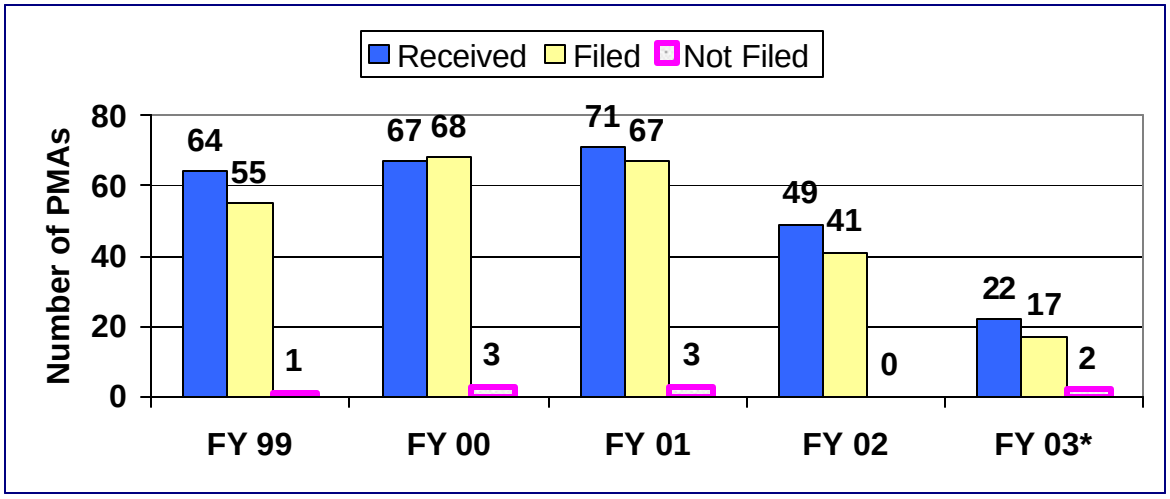
Average FDA review time for original PMAs reaching approval decreased from 161 days in FY 02 to 151 days in FY 03. The non-FDA component of review time increased from 52 days in FY 02 to 70 days this fiscal year. Thus, the total average review time increased to 221 days from 213 days.

Figure 1. Average Review Time for PMA Decision Cohort Approvals



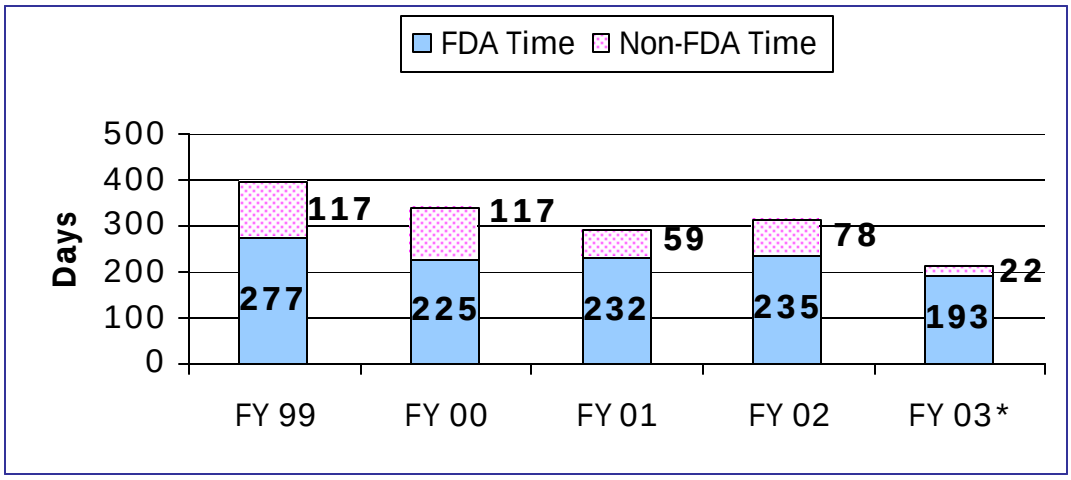
Of greater significance to industry is the total elapsed time from submission to decision. In FY 03, the total average elapsed time for PMA decision cohort performance decreased to 359 days from 364 days in FY 02.

Figure 2. Original Receipt Cohort PMAs Received and Filed



*First six months

Figure 3. Receipt Cohort PMA Average Elapsed Time from Filing to Final Action



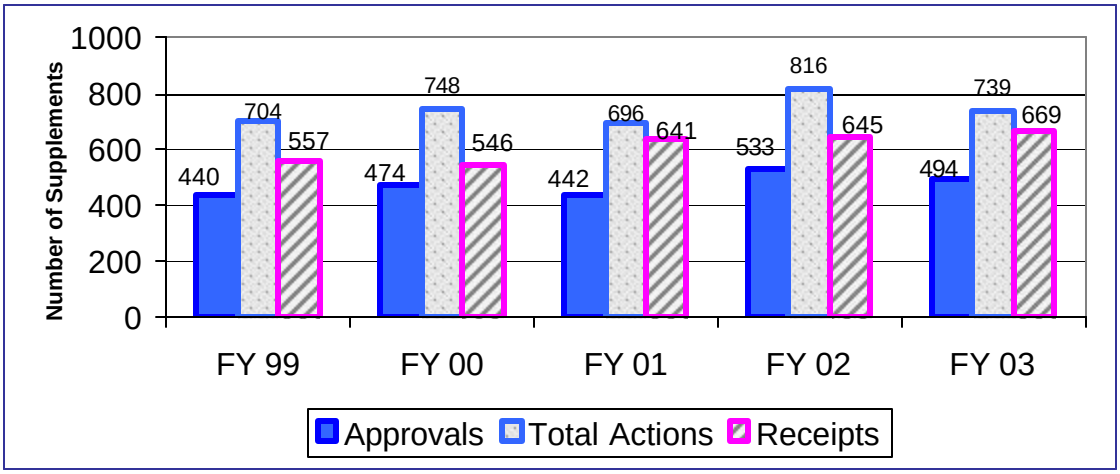
*First six months

For the first 6 months of FY 03 for PMA receipt cohort performance, the average FDA days from filing to first action increased from 136 in FY 02 to 144 days.

The average FDA (total) elapsed time to an approval or to a denial decreased from 235(313) in FY 02 to 193(215) days in FY 03 (see Figure 3). The median FDA (total) elapsed time to an approval or denial decision decreased from 198(300) in FY 02 to 174(218) days in FY 03. All of the statistics of the PMA receipt cohort for FY 03 indicated that we are making decisions faster.

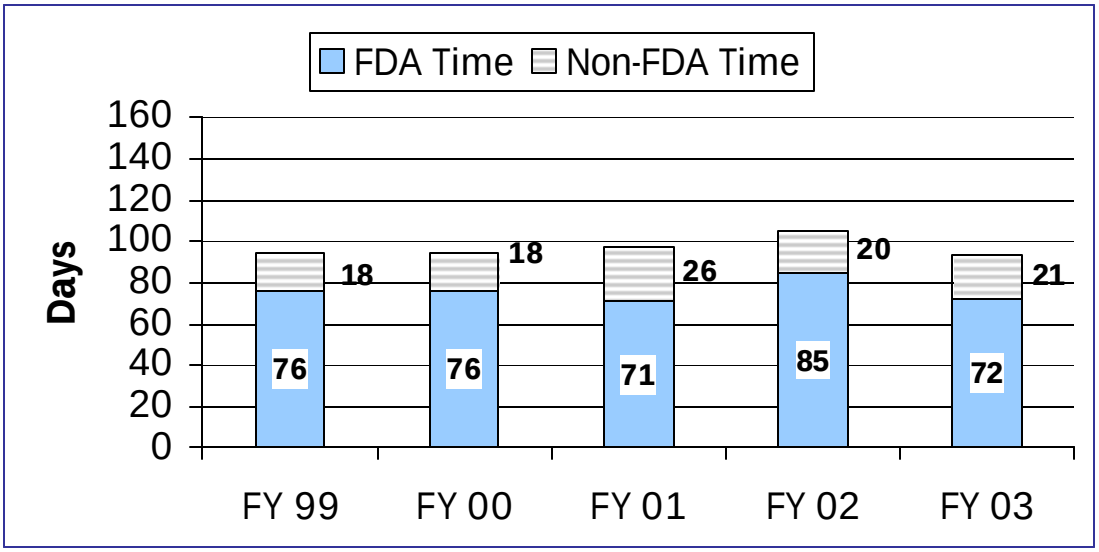
The number of PMA supplements received increased from FY 02's 645 to 669 in FY 03. There were 739 PMA supplement actions which is down from last year's 816 total actions. These actions included 6 panel track PMA supplement filing decisions, 98 scientific review decisions, and 635 approval decisions (see Figure 4).

Figure 4. Annual Receipts and Actions for PMA Supplement Decision Cohort



For PMA supplements reaching final action, the average total review time decreased from 105 days in FY 02 to 93 days in FY 03 (see Figure 5), and the average total elapsed time decreased from 124 days to 111 days.

Figure 5. Average Review Time for PMA Supplement Decision Cohort Final Actions



There were 4 PMA supplements active and overdue at the end of this fiscal year. The number of active supplements decreased to 123 in FY 03 from 127 in FY 02, and the number of supplements on hold increased from 97 to 111. We received 24 more PMA supplements and are reaching final decisions on fewer, but we are taking an average of 13 less days for the decisions.

For the first 6 months of FY 03 for PMA supplements receipt cohort performance, the first action and final action are as follows. The average FDA days from filing to first action decreased from 71 in FY 02 to 61 days in FY 03. The average FDA (total) elapsed time to an approval or denial decreased from 74(89) in FY 02 to 57(67) in FY 03. The median FDA (total) elapsed time to an approval or denial decreased from 35(43) in FY 02 to 30(36) days in FY 03.

Real-Time Review of PMA Supplements

A total of 193 requests were received and processed for real time PMA supplements in FY 03 which represents 29% of all supplements received. Of those submissions, 164 were approved. Most applicants chose telephone conferencing versus a face-to-face meeting or a videoconference. The majority of these applications were reviewed in DCD (49%) followed by DOED (22%), DGRND (11%), OIVD (10%), DRARD (6%), and DAGID (2%). Overall, average review time from receipt to final approval was 44 days.

Product Development Protocols (PDPs)

No original PDPs were approved in FY 03. Three routine PDP supplements and four "Real Time" PDP Supplements were "approved." Note that a PDP that has been "declared complete" is considered to have an approved PMA. ODE/OIVD continue to encourage the use of the PDP process and will work with interested applicants to fully evaluate their PMA options.

Modular PMA Review

For FY 03 ODE/OIVD received a total of 30 PMA shells and 73 modules. A total of 17 modules were found to be acceptable while 5 received deficiency letters. Seventeen modules were rolled into PMA review during FY 03 because they were under review or on hold at the time the PMA was received. Applicants with modular submissions that were under review or deficient when the PMA was received continued to receive feedback under the PMA for those modules. However, this is based on a small number of submissions achieving PMA approval since modular review was implemented. A tracking system with modular PMA query capability became available during FY 99.

Humanitarian Device Exemption (HDE) Applications

ODE/OIVD received 10 original HDEs, an increase from 5 received in FY 02. The total number of original HDE actions increased from 23 in FY 02 to 26 in FY 03. These actions included 13 filing decisions, 9 review determinations, 2 approval decisions and 2 other final decisions.

A total of 3 first actions were made this fiscal year, a decrease from 6 made last year. The average time from filing to first action decreased from 53 days in FY 02 to 48 days in FY 03.

Sixty-seven percent of the first actions made in FY 03 occurred within 75 days.

In FY 03, the average elapsed time (from filing to final approval) for original HDEs was 248 days, a decrease from 302 days in FY 02. The average FDA time was 152 days, a decrease from 175 days in FY 02. The average non-FDA time was 96 days, a decrease from 127 days last year.

The total number of original HDEs in inventory (active and on hold) at the end of this fiscal year was 10. Of these, 4 were under review and 6 were on hold. There were no active HDEs that were overdue at the end of the fiscal year.

The number of HDE supplements received increased to 29 in FY 03 from 16 in FY 02. There were 37 HDE supplement actions in FY 03, up from 27 in FY 02. These actions included 24 approval, 5 approvable, and 6 not approvable decisions.

A total of 29 first actions for HDE supplements were made this fiscal year, an increase from 17 last year. The average time from filing to first action decreased from 53 days in FY 02 to 37 days in FY 03. Ninety percent of the first actions were made within 75 days.

The average elapsed time (from filing to final approval) for HDE supplements increased from 74 days in FY 02 to 95 days in FY 03. The average FDA time decreased from 60 days in FY 02 to 43 days in FY 03. Non-FDA time increased from 14 days in FY 02 to 52 days in FY 03.

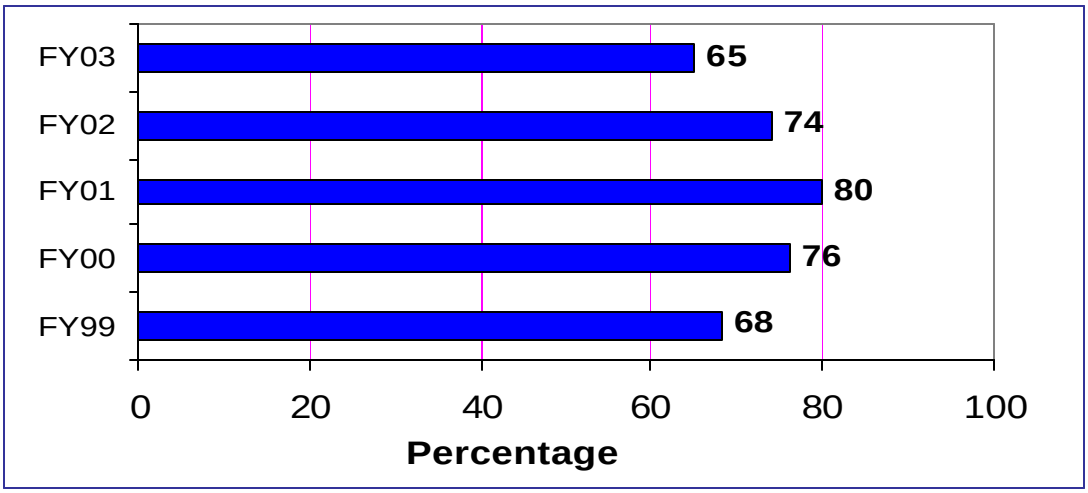
The number of HDE supplements in inventory (active and on hold) at the end of this fiscal year was 11. Of these, 5 were under review and 6 were on hold. There were no active HDE supplements that were overdue at the end of the fiscal year.

Investigational Device Exemptions (IDE)

During FY 03, ODE and OIVD reviewed 309 pre-IDEs. Based on these reviews, guidance for the pre-original IDE submissions were provided through meetings with the sponsors, letters, fax, or by phone.

ODE/OIVD received 242 original IDEs, a decrease from 312 received in FY 02. There were 246 decisions made on original IDEs, a decrease from 307 last year. One hundred percent of all original IDE decisions were issued within 30 days in FY 03. The average review time was 27 days.

Figure 6. Percentage of IDEs Approved on First Review Cycle*



*Based on those IDEs complete enough to permit substantial review.

Of the original IDEs which were complete enough to support substantive review, the percentage of IDEs approved on the first review cycle decreased from 74% in FY 02 to 65% in FY 03 (see Figure 6).

During this fiscal year, 216 IDE amendments were received. Decisions were made on 217 amendments: 73 approvals (34%); 40 disapprovals (18%); and 104 other administrative actions (48%). One hundred percent of these decisions were made within 30 days.

It took an average total time of 180 days to approve IDEs that were initially disapproved, up from 135 days in FY 02. This average approval time consisted of 68 days for FDA time, the same as last year, and 112 days for non-FDA time, up from 67 days in FY 02.

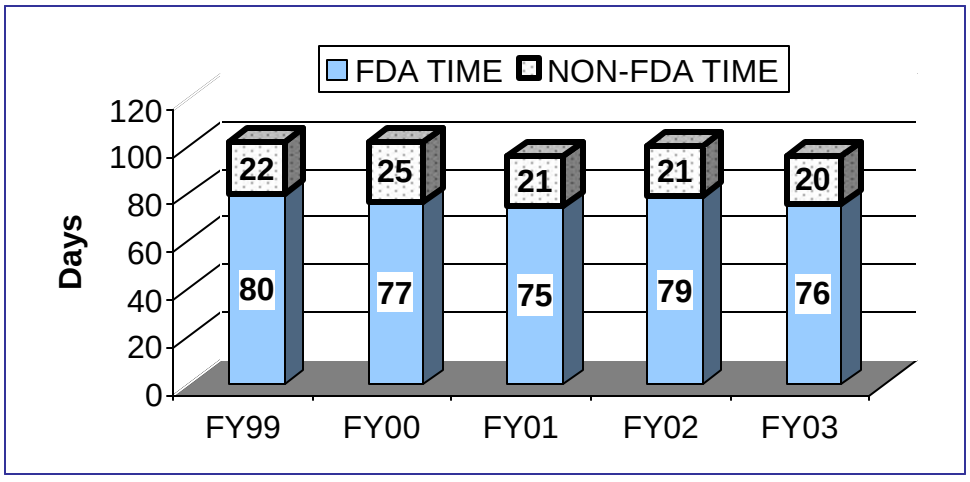
ODE/OIVD received 4,415 IDE supplements during FY 03. There were no overdue supplements at the end of the year, and the percentage of supplements reviewed within the 30-day statutory timeframe was 100% in FY 03. The average review time for IDE supplements was 19 days, down from 20 days in FY 02.

Premarket Notification (510(k)s)

ODE and OIVD received 4,247 original 510(k)s, as well as 1,856 510(k) supplements (responses to hold letters, the receipt of which restart the 90-day review clock), and 1,690 510(k) amendments (additional information received while the 510(k) is under review, the receipt of which does not affect the review clock). Four 510(k)s were granted expedited status.

The total average review time decreased to 96 days in FY 03 from 100 in FY 02, and the average FDA review time was 76 days, down from 79 days in FY 02. The median review time, i.e., the time it took to review 50% of the 510(k)s, has been falling from a high of 164 days in FY 93 to 72 days in FY 03.

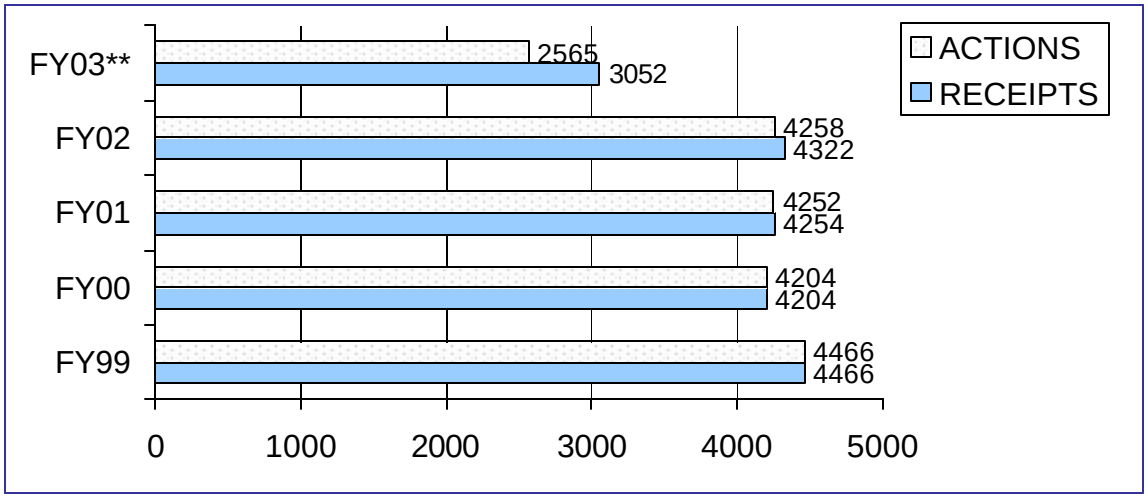
Figure 7. Average 510(k) Review Time for Decision Cohort



There were 1,391 510(k)s in inventory (those under active review or on hold) at the end of this fiscal year. The number on hold at the end of FY 03 was 376. Most important, for the eighth consecutive fiscal year there were no 510(k)s active and overdue at the end of the reporting period.

For the first 9 months of FY 03 for receipt cohort performance, the FDA time from receipt to final decision was 68 days.

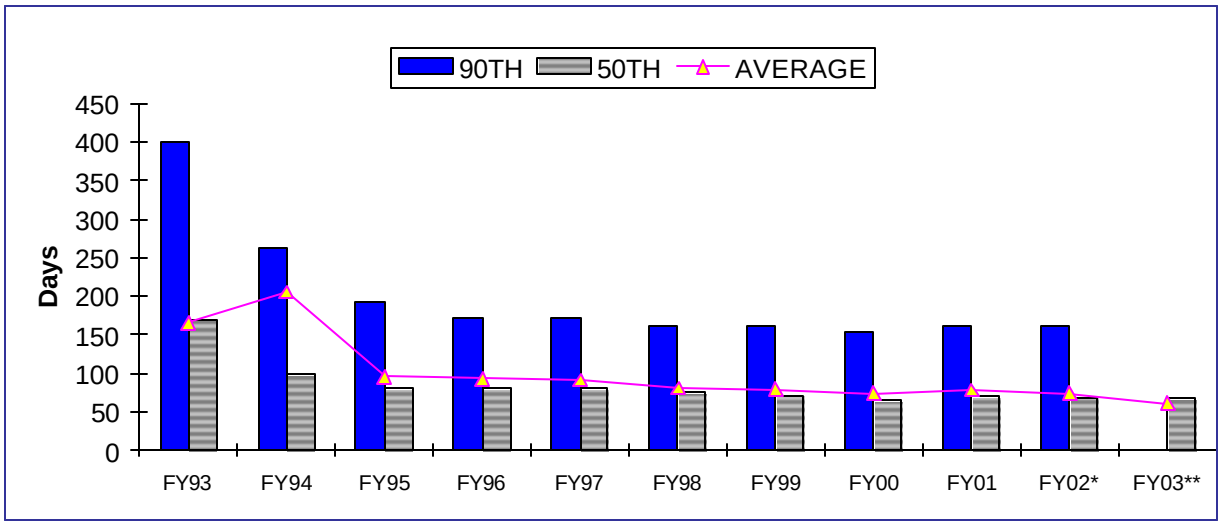
Figure 8. Receipts and Actions for 510(k) Receipt Cohorts*



*Cut Off Date of 9/30/03 for all receipt cohorts.
**12 month projection based on first 9 months of receipts.

For the first 9 months of FY 03 for receipt cohort performance, the total time from receipt to final decision decreased to 73 days.

Figure 9. FDA Days from Receipt to Final Action for 510(k) Receipt Cohorts*



*Cut Off Date as of 9/30/03 for all receipt cohorts.
**For the first 9 months of FY 03. 90th percentile data not available for FY 03.

Third-Party Review of 510(k)s

During FY 03, ODE and OIVD received 190 510(k)s reviewed by third-party organizations under the Accredited Persons provisions (section 523) of the Federal Food, Drug, and Cosmetic Act. This was a 50 percent increase over the 127 submissions received last fiscal year. The increase may be attributable, at least in part, to FDA's implementation of MDUFMA's user fee provisions during FY 03 that require applicants to pay a fee when submitting 510(k)s without a third-party review.

ODE/OIVD made final decisions on 169 "third party" 510(k)s in FY 03, an increase from the 132 final decisions in FY 02. The average total elapsed time from a third party's receipt of a 510(k) to ODE/OIVD's issuance of a substantial equivalence decision was 74 days, as compared to the average total elapsed time of 112 days for the substantial equivalence decisions on comparable 510(k)s that did not have a third-party review. (This comparison is based on "traditional" and "abbreviated" 510(k)s; "special" 510(k)s are excluded because they typically are not submitted to third parties.) Thus, 510(k)s with a third-party review received marketing clearance 34 percent faster, on average, than comparable 510(k)s reviewed entirely by FDA.

Information on the 510(k) Accredited Persons Program is available on the Center's third party web page at http://www.fda.gov/cdrh/thirdparty/ .

Special 510(k)s

From October 1, 2002 to September 30, 2003 ODE/OIVD received 864 Special 510(k)s out of the 4,247 total number of 510(k)s received. Of these 831 have received final decisions (792 were found substantially equivalent, 7 were found not substantially equivalent, and the remaining 32 had other decisions such as withdrawn or deleted) with the average FDA review time of 28 days and the average total time of 34 days.

Abbreviated 510(k)s

During this fiscal year, ODE/OIVD received 206 *Abbreviated* 510(k)s out of the 4,247 total number of 510(k)s received. Two hundred twelve received final decisions (165 substantially equivalent, 3 not substantially equivalent, and 44 other decisions) with a FDA average review time of 96 days and total time of 119 days.

ODE/OIVD Device Guidance Documents

By the end of this fiscal year, ODE and OIVD issued 26 final guidance documents and issued another 5 drafts for comment. Of the 31 total, 6 were specifically related to MDUFMA (1 Blue Book and 6 Guidance). ODE/OIVD guidance documents issued this year are listed under Part 2 – Industry Information.

Scientifically sound guidance protects and promotes public health by helping ensure manufacturers conduct the correct device performance testing and clinical trials and by enhancing FDA's ability to review study results, bringing beneficial products to market without undue delay.

Guidance Development Templates

The need for clear science communication in guidance documents and the need for a streamlined procedure for developing certain kinds of guidance documents has led to an exceptionally useful innovation in ODE/OIVD guidance development. In collaboration with the Regulations Staff in the Office of Health and Industry Programs and the FDA Office of Chief Counsel (OCC), ODE/OIVD developed template formats for Class II special controls guidance documents. We have also developed templates for special controls for devices that are exempt from 510(k) and templates for non-special controls guidance documents.

This year, ODE/OIVD also created instructions to authors of guidance, a format for concept papers for guidance developed with the use of templates and other Plain Language materials for science writing in ODE/OIVD.

The use of templates and these associated materials in guidance development has contributed to our efforts to reclassify, more efficiently, numerous preamendments class III devices helping to reduce regulatory burden while still ensuring that the risks to health associated with the device are appropriately addressed in the premarket review. Our efforts in creating templates for special controls guidance documents used in *de novo* classification have helped ODE/OIVD meet statutory timeframes for these submissions as well.

Risk Management in Guidance Development Templates

Guidance is an effective risk management tool and a critical element of the Commissioner's Strategic Plan. Moreover, clear, accurate scientific communication in guidance reduces the burden on both industry and FDA. The opportunity to incorporate FDA recognized standards in guidance provides industry and FDA with testing methods and acceptance criteria vetted by experts who represent the international device community, further ensuring clear communication and reducing the burden of regulation. All of ODE's and OIVD's guidance development templates focus on addressing the risks to health associated with the use of devices and the measures FDA has identified to mitigate those risks, measures that follow the systems theory approach, by showing how quality systems requirements, premarket review, and postmarket oversight serve together as a system of regulatory controls to assure the safety and effectiveness of devices marketed in the U.S.

Significant Medical Device Approvals

During FY 03, ODE and OIVD approved 11 PMAs and cleared 8 510(k)s that represent significant medical device breakthroughs. See Part 2 - INDUSTRY INFORMATION, Significant Medical Device Approvals - for a complete listing.

Reclassification Petitions

Any interested person may submit a petition to the agency for reclassification of a device, e.g., from class III to class II, or class II to class I. Additionally, the agency on its own initiative, may follow procedures to reclassify a generic type of device. There are five sections under the Federal Food, Drug, and Cosmetic Act by which we may reclassify a device, section 513(e), 513(f) 514(b), 515(b) and 520(l) depending on the status of the device type, such as new device types found to be not substantially equivalent or transitional devices formerly regulated as drugs. The reclassification petition needs to contain sufficient information to allow FDA to determine that the proposed classification can provide reasonable assurance of safety and effectiveness. Reclassification petitions and their final decisions are put on public display at the Dockets Management Branch.

Proposed Classification Actions

- Published a proposed rule in the *Federal Register* on October 22, 2002 to classify the Human Dura Mater into class II.

- Published a proposed rule in the *Federal Register* on March 20, 2003 to classify the Silicone Sheeting into class I exempt from premarket notification.

Final Classification Actions

- Published a final rule classifying the medical washer and medical washer-disinfector intended for general medical purposes to clean and dry surgical instructions, decontaminate or disinfect anesthesia equipment, hollowware, and other medical devices into class II (special controls). [Effective December 16, 2002]

- Published a final rule classifying resorbable calcium salt bone void filler device intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure into class II (special controls). [Effective July 2, 2003]

Proposed Reclassification Actions

- Published a proposed rule in the *Federal Register* on December 13, 2002 to reclassify the arrhythmia detector and alarm from class III (premarket approval) to class II (special controls) based on new information regarding the device. FDA is also proposing to revise the identification of the arrhythmia detector and alarm to separate the automated external defibrillatory (AED) from the identification of the arrhythmia detector and alarm.

Final Reclassification Actions

- Published a final rule in the *Federal Register* on December 19, 2002 to reclassify the Adsorbable Polydioxanone Surgical Suture from class III to class II. [Effective July 17, 2002].

- Published a final rule in the *Federal Register* on December 31, 2002 reclassifying the cutaneous carbon dioxide (PcCO2) monitor from class II (performance standards) into class II (special controls). FDA also reclassified the cutaneous oxygen (PcO2) monitor for an infant patient who is not under gas anesthesia from class II (performance standards) into class II (special controls) and is reclassifying the cutaneous oxygen (PcO2) monitor for all other uses from class III (premarket approval) into class II (special controls).

- Published a final rule in the *Federal Register* on March 24, 2003 to reclassify the Knee Joint Patellofemoral Metal/Polymer Porous-coated Uncemented Prosthesis and the Knee Joint Femoraltibial (Unicompartmental) Metal/Polymer Uncemented Prosthesis from class III to class II. [Effective February 3, 2003].

Automatic Evaluation of Class III Designation

- Issued an order on April 30, 2003 classifying NIOX Breath Nitric Test System into class II CFR 862.3080

- Issued an order on June 16, 2003 classifying Endotoxin Activity Assay into class II CFR 866.3210

- Issued an order on July 8, 2003 classifying West Nile Virus IgM Capture ELISA Assay into class II CFR 866.3940

513(g) Submissions

Under Section 513(g) of the Federal Food, Drug, and Cosmetic Act, a person can request information about the classification of a device and the regulatory requirements applicable to the device. Within sixty days of the receipt of such a request, the Office of Device Evaluation (ODE) or the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) will provide a written response to such request.

During this fiscal year, ODE and OIVD received 156 513(g) requests for information. ODE and OIVD have responded to 135 of these requests, while reviews of the remaining 21 requests were ongoing.

Part 4 – Major Program Initiatives

Performance Scorecards

The ODE and OIVD management teams received formal training and actively participated in the Center's initiative to develop office and division-level Performance Scorecards. These Performance Scorecards contain a series of performance measures that are linked to the offices' performance goals and CDRH's strategic plan. In FY 04, ODE and OIVD will establish baseline data for the performance measures and report initial performance results from these Performance Scorecards.

In addition five ODE employees and one OIVD employee were formally certified as Performance Improvement Coaches for Performance Scorecards and Continuous Process Improvement.

Continuous Process Improvement (CPI)

Continuous Process Improvement involves identifying a process that needs to be improved, analyzing the current process, researching potential improvements, and developing and implementing an improved process. The improved process ultimately will assist the Offices' in meeting performance measures identified in the Offices' Performance Scorecards. ODE and OIVD processes that were subject to formal Continuous Process Improvement efforts in FY03 were PMA Filing, PMA Close-Out, and Turbo 510(k).

Guidance Documents and Standards

During the fiscal year, Center management initiated an effort to speed the development of guidance documents in an effort to reduce regulatory burden, foster greater consistency in scientific evidence provided in premarket submissions and optimize our evaluation processes to achieve the MDUFMA performance goals. ODE's Deputy Director for Science and Regulatory Policy, in collaboration with the Office of Science and Technology, began efforts to involve scientists from throughout the Center in the guidance development process. Furthermore, specific efforts are underway to insure that FDA recognized consensus standards are fully integrated into appropriate guidance documents in an attempt to further streamline the FDA review and promote greater international harmonization.

ODE/DRARD/Epi Pilot Project

As part of ODE's effort to formalize Total Product Life Cycle precepts within the premarket review process, the Division of Reproductive, Abdominal, and Radiological

Devices (DRARD) participated in a pilot cooperative project from February 2002 to February 2003 with the Epidemiology Branch (EB) of the Office of Surveillance and Biometrics. The purpose of the project was 1) to determine when and how the EB could best provide appropriate input/recommendations to DRARD regarding potential postmarket investigations and 2) to initiate, and later evaluate, product-specific Postmarket Plans. Over the course of the year each epidemiologist participated in the review of a PMA being evaluated by DRARD. Two of the PMAs that were approved during the year had post approval studies. In both cases the epidemiology reviewer played a large role in the study design. There were also a few "firsts" that took place during the pilot project. This was the first time that the EB was involved with an expedited PMA and the first time well-defined Postmarket Plans were developed prior to device approval. It was also the second time that the EB made a presentation to the panel as part of the FDA presentation of the PMA. Both groups believed that the involvement of the EB in the PMA review enhanced the review process. All participants believed that early involvement was the best approach. Both sides believed that there was not enough experience gained from just one year, but that the collaboration looked very promising. Therefore the decision was made to continue and refine the pilot project over the next year.

Creation of the Office of In Vitro Diagnostic Device Evaluation and Safety

The Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) was established on November 17, 2002, and combines the functions of all the offices within Center for Devices and Radiological Health (CDRH) into one organizational unit for cradle-to-grave regulation of in vitro diagnostic devices (IVDs). It carries out this mission by combining the pre-market review responsibilities of Office of Device Evaluation (ODE), the enforcement responsibilities of Office of Compliance (OC), and the post-market surveillance responsibilities of Office of Surveillance and Biometrics (OSB). To support these regulatory responsibilities, OIVD maintains strong ties to Office of Science and Technology (OST) for technical assistance, Office of Health and Industry Programs (OHIP) for communication and outreach assistance, and Office of Systems and Management (OSM) for program management assistance.

OIVD consists of a multidisciplinary group of scientists and other professionals who are collectively dedicated to promoting and protecting public health through clear and consistent regulation of IVDs by applying good scientific principles throughout the Total Product Life Cycle of the device. OIVD has a dual charge to foster the rapid transfer of good new IVDs into the medical market while preventing marketing of unsafe or ineffective devices. The Office strives to ensure the work is transparent in order to allow all stakeholders to obtain the knowledge required to make informed decisions about the development, production, and use of IVDs. In addition, OIVD administers the Clinical Laboratory Improvement Amendments (CLIA) '88 complexity program for the Centers for Medicare and Medicaid Services (CMS) by categorizing commercially marketed in vitro diagnostic tests by level of complexity.

Creation of OIVD Webpage

Consistent with CDRH's center-wide "Knowledge Management" and "Transparency" initiatives, OIVD launched the OIVD webpage on February 2003. The URL for the OIVD webpage is: http://www.fda.gov/cdrh/oivd/. The OIVD webpage is designed to serve as one-stop-shopping for all the OIVD customers, the FDA staff, the public, the public heath professionals, the academicians, and the regulated industry.

The webpage supports the OIVD's "Transparency" initiative by allowing the monthly posting of the "Decision Summary Templates". The Decision Summary Template is a standardized template where, at a glance, one can understand the basis for clearance of a particular in vitro diagnostic 510(k) submission. This program has been in place since August 1, 2003. To see these Decision Summaries for all 510(k) clearances since August 1, 2003, go to the following link from the OIVD home page: Search All Cleared/Approved OIVD Products

The webpage supports the OIVD's "Knowledge Management" initiative by allowing consumer access to the data base for Home Use Lab Tests [Over-the-Counter (OTC) tests] and collection kits that have been cleared or approved by the FDA. To see information related to OTC IVD products go to OIVD homepage and under Quick Links, click on Over-The-Counter Tests or use the following link to get access to the OTC data base: http://www.fda.gov/cdrh/oivd/consumer-otcdatabase.html

Another very useful "Knowledge Management" tool on the OIVD webpage is the Lab Safety Tips link that appears on the home page under Laboratory Information. This section gives information about maintaining a safe clinical laboratory environment. It offers lab safety tips related to patient care and management as it relates to using a variety of in vitro diagnostic tests. The Lab Tips provide the OIVD customers, the public, the public health professionals, and the laboratorians, with precautions and limitations when using a particular IVD. The Lab tips contain a discussion of quality control and quality assurance, details about reporting IVD problems, and resources for additional information.

OIVD Patient Safety Team

Early in 2003 the Patient Safety Team (PST) was formed in OIVD as a part of a larger Total Product Life Cycle (TPLC) program. The team crosses all OIVD divisions and several offices including representatives from OSB, OST, OHIP and OSM. The team's mission is two-fold. First, to explore new avenues to obtain timely, useful and accurate postmarket information on the devices we regulate in order to feed this information back to the premarket review; and second, to facilitate the merger of pre- and postmarket activities to smooth the transition to the TPLC concept. The team now serves as the "umbrella" team to oversee several project teams summarized below.

IVD MedSun/LabSun Pilot Team - During the last year the LabSun Pilot team has been very active. The team designed two report forms: a short form for minor events in the laboratory where patients were not directly impacted and a longer report form for incidents of more significance. Working with CODA, the contractor for the MedSun Project, the team recruited and trained nine sites in the Maryland, Virginia and DC area for a currently ongoing four month pilot of laboratory reporting. We have already had several reports come in, one resulting in a compliance investigation.

IVD Listserv Team - The team has been participating in passive listening on several listservs and feeding issues back to the PST, the postmarket staff, and the respective divisions. There have been several incidences where discussion topics which were monitored resulted in compliance actions or in OIVD posting Lab Safety Tips on the OIVD website.

Patient Safety News Team - The Patient Safety News (PSN) team participates on the PSN editorial board that includes CDER, CBER and CFSAN in addition to CDRH. The board meets once a month to discuss upcoming stories and review literature and journal articles related to patient safety. This outreach activity delivers potentially life-saving information to health practitioners. PSN stories include: safety alerts and product recalls; ways to protect patient and prevent medical errors; products recently approved by FDA; and important FDA decisions and actions. Several OIVD products have been featured in the program.

Adverse Event Reporting Activity and Transition to OIVD Team - At each PST meeting, the team was updated on newly received adverse event reports that met criteria the PST specified – deaths, hospitalization, and voluntary reports. Two computer-based training sessions on review and analysis of adverse event reports were conducted by OSB analysts. Currently, nine OIVD staffs are being trained as analysts. On August 22, OIVD staff began to receive IVD adverse event reports directly and to manage their follow up. The OIVD analysts group meets regularly to discuss problems and issues. Each analyst reports adverse events regularly to the respective OIVD Division in order to integrate information from the reports into premarket reviews.

CMS Collaboration Team - OIVD met with CMS to discuss new opportunities for collaboration. Pending finalization of a memorandum of understanding, review scientists from OIVD will work with coverage analysts from CMS on general issues of joint interest, including projects related to pharmacogenomics and cervical cancer. OIVD and CMS will explore mechanisms by which they can increase sponsor awareness of how they can best meet the regulatory requirements of each agency for devices using new molecular technologies.

Outcomes Team - This team was formed to establish a process to measure both short and long term public health impact associated with the FDA clearance or approval of IVDs. This could include clinical outcomes associated with the IVD itself or those specifically associated with CDRH interventions such as labeling changes or the

provision of critical information to the public. They selected four products or product types to follow by literature search, meta analysis and postmarket reporting. The overall goal is to evaluate OIVD's role in improving the quality of health care. In the process, they hope to establish contacts at CDC, NIH and CMS. CMS has expressed interest in participating with the group.

Training Team - There were several sessions of training given by OSB including an overview of OSB, a session on how MDRs are processed and the first two MAUDE database training sessions. Several members of the PST also participated in FDA/Industry roundtable meetings to discuss the postmarket reporting system.

Part 5 – Other Program Activities

ODE Implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)

During FY 2003, ODE invested considerable effort to ensure a smooth implementation of MDUFMA. MDUFMA provides essential additional resources to the device evaluation program and, in turn, establishes a comprehensive set of very challenging device review performance goals for fiscal years 2003 through 2007. The past year's efforts have focused on laying the groundwork to ensure we will be able to meet these performance goals. During FY 2003, we drafted guidance for FDA staff and industry, developed new data systems to track performance, worked with stakeholders to develop agreement on the basic direction of the program, and began to hire additional medical, technical, and scientific staff. We will build on these efforts in FY 2004 and the future.

Additional information concerning our implementation of MDUFMA is available in CDRH's FY 2003 annual report, and at www.fda.gov/cdrh/mdufma/. The MDUFMA Internet site provides the full text of the new law, useful reference materials, all of our MDUFMA guidance documents, and links to FDA's FY 2003 report to Congress on our progress towards meeting MDUFMA's performance goals.

Guidance for Industry and Reviewers

In FY 03, ODE/OIVD published 25 final guidance documents and published 6 draft guidance documents for comment. See INDUSTRY INFORMATION for a complete listing of all ODE guidance documents published in FY 03.

Public Health Response

OraQuick® Rapid HIV-1 Antibody Test: In November 2002, the FDA/CBER Approved OraQuick® Rapid HIV-1 Antibody Test manufactured by OraSure Technologies, Inc., of Bethlehem, Pa. The test is the first rapid HIV point-of-care (i.e., testing and results are available in one visit) test approved by the FDA. It is also the first test for HIV that OIVD has waived under the Clinical Laboratory Improvement Amendments (CLIA). Following the CLIA waiver by OIVD the HHS Secretary Tommy G. Thompson announced that HHS has extended the availability of the OraQuick Rapid HIV-1 Antibody Test from 38,000 laboratories to more than 100,000 sites, including physician offices and HIV counseling centers. The Secretary added "Ensuring the widespread availability of a rapid HIV test to outreach services in communities where people are at high risk of HIV is vital to the public health, without today's action (CLIA Waiver), this test would be limited to use in laboratory settings where many high-risk people do not go for testing."

Widespread availability of the rapid HIV test is likely to increase overall HIV testing and decrease the number of people -- an estimated 225,000 Americans -- who are unaware they are infected with the HIV virus. Early testing enables infected individuals to obtain medical care earlier in the course of their infection, potentially saving lives and limiting the spread of this deadly virus.

SEVERE ACUTE RESPIRATORY SYNDROME (SARS): An IDE for a SARS Coronavirus, submitted by HHS, Centers for Disease Control and Prevention (CDC), was approved. This allowed CDC to make available to about 100 public health laboratories nationwide, a new experimental laboratory test for patients suspected of being infected with the SARS virus. The experimental diagnostic test was rapidly developed by CDC over the past few months in an urgent effort to address this pressing public health need. HHS, Food and Drug Administration (FDA) worked closely with CDC to develop appropriate information for patients and health professionals in order to make the test available on an investigational basis. Because information about the test's performance is still being collected, patients will be asked for written consent before the test is used.

OIVD Compliance Activities

Class I Recalls

8/11/03 (Recall number Z-1094-03), Becton Dickinson Diagnostic Systems, BD ProbeTec™ ET Instrument. The incorrect installment of fiber optic bundles, exposed patients screened by this device to a risk of life threatening consequences due to inaccurate test results.

9/10/03 (Recall number Z-1209-03), bioMerieux, Inc., VIDAS® Chlamydia Assay. The raw material (bovine serum albumin (BSA)) caused an accelerated degradation of the product's performance leading to false negative results, exposing patients screened by this device to a risk of potentially life threatening consequences due to inaccurate test results.

Warning Letters

10/10/02, Eagle Diagnostics, Inc., in vitro diagnostic devices. The warning letter references adulterated devices, misbranded devices, catalog listings of unapproved devices, and registration issues.

3/28/03, Applied Imaging Corporation, ariol SL-50 automated image analysis system (ariol SL-50). The warning letter references adulterated, unapproved and misbranded device issues.

Bioterrorism Preparedness

ODE and OIVD continue to be involved in several resource-intense initiatives related to national bioterrorism preparedness and response. ODE and OIVD established liaisons and continue collaborate with other government agencies and the military to prepare for and assume regulatory responsibilities applicable to in vitro diagnostic products and other medical devices that are critical to bioterrorism preparedness efforts. ODE and OIVD are currently developing guidance and procedures for timely premarket review and approval of these devices.

The medical and public health preparedness and response to bioterrorism threats include the identification of threat agents by using in vitro diagnostic devices. Most laboratory reagents and test kits used for the identification of threat agents are not routinely used in the clinical laboratory and have not been cleared or approved by FDA. Some have not been classified. OIVD is developing notices of proposed rule making (NPRM) describing the proposed classification of *B. anthracis* and *Y. pestis*, and guidance containing the types of information needed to assess premarket submissions of the devices FDA is proposing to classify. OIVD is also working on the NPRM that proposes an amendment to the exception from general requirements for informed consent to apply in certain circumstances when investigational IVDs are used to identify agents potentially associated with terrorism threats.

In addition, OIVD continues interacting with manufacturers involved in the development and data gathering on devices for the identification of bioterrorism threat agents. This year OIVD has met or communicated by phone with several companies to clarify the premarket review requirements and routes available to obtain clearance or approval for medical uses, including investigational uses. Our scientists have participated in discussions with industry, the CDC and the military in determining options for making new in vitro diagnostic devices available and in clarifying requirements for testing during the investigational phase of the products.

Least Burdensome

The two sections of the Food, Drug, and Cosmetic Act (the act) commonly referred to as the “least burdensome provisions” were enacted by Congress in 1997 to ensure the timely availability of safe and effective new products that will benefit the public and ensure that our Nation continues to lead the world in new product innovation and development. During the last few years, CDRH has been working with its stakeholders to develop an interpretation of the least burdensome provisions. In the May 3, 2001, Federal Register, the draft guidance document entitled, “The Least Burdensome Provision of the FDA Modernization Act of 1997: Concept and Principles” was released for comment. While the agency received very few comments on the draft, almost all of them strongly supported the guidance and encouraged full implementation of it as soon as possible. Several comments recommended that FDA develop a training program for its staff as well

as ways to assess both the Agency's success in implementing the principles and the stakeholders' satisfaction with FDA's incorporation of them into its daily activities. The agency agreed with these recommendations and has incorporated them into the final guidance. The final document was released on the internet on September 30, 2002 and in the October 4, 2002 Federal Register (67 FR62252). The guidance may be found on the Center's website at www.fda.gov/cdrh/ode/guidance/1332.html.

Study Determination Inquiries

Every year, the Office of Device Evaluation (ODE) receives numerous inquiries regarding the need to submit an IDE application for research involving medical devices. These inquiries are received through a variety of means - in meetings, by telephone, e-mail, fax or letter. Such inquiries are initiated by a wide variety of entities, including device manufacturers, clinical investigators, and IRB members. In order to respond to these inquiries, we may refer to the IDE regulation (21 CFR 812), particularly sections 812.1 (Scope), 812.2 (Applicability), and 812.3 (Definitions), and the FDA Information Sheet entitled, "Significant Risk and Nonsignificant Risk Medical Device Studies" (hereafter referred to as SR/NSR guidance).

Often, the inquiries we receive can be easily answered by referring to the sources identified above. Occasionally, inquiries will present new situations not clearly identified in the regulation or the SR/NSR guidance. A few inquiries involve the scope of the IDE regulation and/or jurisdictional issues that may require consultation with the other FDA centers. An IDE Memorandum (#D01-1) dated, October 26, 2001 was issued to establish written procedures for handling inquiries regarding the need for an IDE application for research involving medical device.

When responding to these inquiries, there are three possible responses: the research is exempt from the IDE regulation; the abbreviated IDE requirements must be met (nonsignificant risk [NSR] study); or the full requirements of the IDE regulation must be met, that is, an IDE application must be submitted to FDA (significant risk [SR] study). In FY 03 ODE received 49 inquires. Of the 49 inquires, there were 13 SR determinations, 13 NSR determinations, 22 exempt determinations, and 6 inquires still under review.

Significant Jurisdictional Issues

Title 21 of the Code of Federal Regulations Part 3 - PRODUCT JURISDICTION describes the procedure the agency uses to assign Center jurisdiction over medical products whose jurisdiction is not clear or is in dispute. Requests for Designations (RFDs) over such products are made in writing to the Office of Combination Products which took this role over from the Office the Chief Mediator and Ombudsman in mid-FY 03. These formal submissions contain the material describing the requester's product and/or products, a proposal regarding which Center should be given lead designation over their product, and whose authorities (Biological, Device or Drug) should apply.

In FY 03 CDRH participated in the review of 26 out of 34 RFD's received by the FDA's Ombudsman's Office, in addition to completing the reviews of 5 RFDs received in FY 02. The reviews of the new requests were assigned to the ODE Divisions as follows: DGRND was assigned 11 (eleven); DRARD was assigned 9 (nine); DAGID and DCD were each assigned 2 (two); and POS was assigned 1 (one) to review. The remaining RFD was assigned to OIVD to review.

Of the 31 RFD's [26 assigned in 2003 and the 5 carry over from 2002] which CDRH completed reviews of in FY 03 by both ODE and OIVD:

- CDRH was assigned the lead center in 14 of those requests
- CDER was assigned lead center in 8
- CBER was designated lead in 6 RFDs
- One was ruled by the Office of Combination Products as not an FDA regulated product and
- 2 were not due for completion until FY2004.

CLIA Activities

Congress passed the Clinical Laboratory Improvement Amendments in 1988, establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The categorization of commercially marketed *in vitro* diagnostic tests under CLIA has been the responsibility of the FDA since January 31, 2000. OIVD performs the CLIA complexity categorization that includes the assignment of these test systems to one of three CLIA regulatory categories (high, moderate and waived) based on their potential risk to public health. During FY 03 OIVD performed categorizations on a total of 2170 tests including 215 High, 1661 Moderate, and 194 Waived tests. FDA, CMS, and CDC are working together to publish a final rule on CLIA waiver. More information on the CLIA program can be found at http://www.fda.gov/cdrh/clia/index.html.

TSE (Transmissible Spongiform Encephalopathy)

ODE has been an active participant in both agency and CDRH TSE activities. As a member of the CDRH Transmissible Spongiform Encephalopathy (TSE) Working Group, ODE helped develop a TSE risk document to address medical device TSE risk issues.

ODE joined the other CDRH offices and CDER, CBER, and CFSAN in the Center for Biologics July 17-18, 2003 FDA CBER TSE Advisory Committee (TSEAC) meeting. ODE was responsible for planning the medical device portion of the meeting, including recruiting speakers, developing the agenda and making presentations regarding decontamination of medical devices that have been exposed to TSE. At the TSEAC meeting, ODE was evidence of the CDRH TSE WG FDA wide collaboration. In addition to ODE, all other offices in CDRH participated along with other centers in FDA - CBER,

CDER and CFSAN all developed sessions and shared information. At the TSEAC meeting, ODE and OST initiated a 2 hour session with the panel experts where medical device questions related to decontamination of medical devices and equipment used in manufacturing were presented to the expert CBER panel that included an ODE panel expert on infection control. This participation by ODE and the comments from the panel provided the opportunity to initiate discussion on TSE decontamination of medical devices at this public meeting with HHS, industry and international attendance. The TSEAC panel recommended a workshop to further assess the current state of knowledge of decontamination/inactivation of TSE for medical devices, facilities, and other medical applications of animal derived products. ODE is presently taking the lead in the CDRH TSE Working Group efforts to investigate the potential benefits of an international workshop on medical device decontamination.

Advisory Panel Activities

The Center's Medical Devices Advisory Committee (MDAC) with its 18 panels provide clinical and scientific advice to FDA in several areas of activity fundamental to the regulation of medical devices. The most significant of these areas of activity are: (1) classification and reclassification of medical devices into one of three classes based on risk, (2) review and make recommendations on premarket submissions such as Premarket Approval Applications (PMAs), Product Development Protocols (PDPs), and Premarket Notification submissions (510ks), (3) provide advice on guidance documents which convey to industry and the agency staff FDA's expectations for studies and data for premarket review, and (4) provide input on issues or problems concerning the safety and effectiveness of medical devices.

In FY03, ODE held thirteen panel meetings. The panels reviewed and made recommendations on: twelve PMAs, one 510(k), two reclassification petitions, and three general issues. In FY03, there were 12 training sessions for members and consultants. The panels reviewed PMAs for significant medical device breakthrough technologies such as a drug-coated coronary artery stent and a stair climbing wheel chair.

A new draft guidance document, "Pediatric Expertise for Advisory Panels" issued for comment on June 3, 2003. This guidance document describes the process that CDRH intends to follow to ensure that an advisory panel review of a PMA or 510(k) includes pediatric specialists on the panel, when appropriate. The website for this draft guidance document is: http://www.fda.gov/cdrh/ode/guidance/1208.pdf. This year, the Center has recruited more than twenty pediatric specialists to serve as a member or consultant on an advisory panel for any premarket submission that may be indicated for use in a pediatric subpopulation.

CDRH continuously recruits highly qualified experts to serve as members and consultants on our panels. Potential candidates are asked to provide detailed information concerning financial holdings, employment, and research grants and contracts to identify any potential conflict of interest. Interested individuals should send their curriculum vitae to njp@cdrh.fda.gov.

The MDAC advisory panels are key to ensuring that the agency has access to the nation's most esteemed medical experts and to making the FDA medical device review process transparent to stakeholders. The Office of Device Evaluation greatly appreciates the significant contributions that the advisory panel members and consultants make to the medical device review program.

ODE Integrity Program

During this fiscal year, ODE/OIVD considered about 41 cases concerning the integrity of data submitted to the agency in premarket applications. Under the Application Integrity Program (AIP), one firm was placed on the AIP list and AIP restrictions applied against this firm, while AIP restrictions were removed from two firms. An Integrity Hold was placed on two firms' applications during FY 03.

ODE handled 29 instances related to questions arising under the standards of conduct for employees. During FY 03, as in years past, the ODE/OIVD staff received several unsolicited gifts from the regulated industry. Both the offering of gifts and their acceptance in general, are prohibited under applicable laws and regulations. The regulated industry, their agents and representatives should not send gifts to staff members. See Standards of Ethical Conduct for Employees of the Executive Branch on the internet at http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/reference/rfsoc_99.pdf.

Part 6 - Program Support

Freedom of Information Requests

Staff from ODE and OIVD received 512 FOI requests during FY 03, a decrease from 739 in the last fiscal year. During FY 03, the number of FOI requests closed was 836 compared to 1,141 in FY 02. The total number of FOI requests pending in ODE and OIVD at the end of FY 03 is 207 compared to 345 in FY 02.

Congressional Inquiries

Staff from ODE and OIVD responded to Congressional inquiries and participated in briefings on the following topics -- user fees, breast implants, dental amalgam, plano contact lens, contact lenses, temporomandibular joint implant or TMJ, bovine spongiform encephalopathy or BSE, the Medical Device User Fee and Modernization Act of 2002 or MDUFMA, electromagnetic treatment devices, and condoms. ODE and OIVD also participated in hearings of Congressional committees and briefings of Congressional staff during FY03. These topics dealt with FDA's budget, counter terrorism, human tissue, dental amalgam, and FDA's efforts to combat the SARS outbreak.

Publications

During FY 03, ODE staff authored 33 manuscripts for publication in professional and scientific journals and delivered 103 presentations at professional, scientific and trade association meetings. See Appendix B for a bibliography of publications.

OIVD staff authored 6 manuscripts for publication and delivered 18 presentations. See Appendix C for a bibliography of publications.

ODE Vendor Day

In FY 03, ODE did not schedule any Vendor Days.

Site Visits

In FY 2003, ODE continued its Site Visit Program that was developed in 1993 to enhance reviewer knowledge of how specific medical devices are designed, manufactured, and tested. The program continued to include not only visits to medical device manufacturing firms but also to hospitals for the observation of certain devices in use. Twenty-one firms and/or hospitals were visited by 194 scientific reviewers to learn about such things as laser refractive surgery, di Vinci robotic system, left ventricular assist device, catheters, anesthesiology, breast implants, vascular stents, MR-guided focused ultrasound ablation

of uterine fibroids, antimicrobial testing for new surface modification, cardiac electrophysiology devices, spinal implants, fecal incontinence devices, ophthalmic contrast sensitivity, and other devices.

Mentoring Program

ODE's mentoring program is designed to orient new employees to their job responsibilities and their workplace. The program matches a new employee with a mentor who is expected to provide technical, informational and career guidance to the employee in an effort to enable employee assimilation into the workforce and to ensure appropriate employee development. The ODE PMO Office has served as an informal mentoring agent for minorities.

Recruitment

To enhance the Center effort to increase the hiring of minorities and those with a disability, ODE participated in the 2003 Workforce Recruitment Program (WRP) for College Students with Disabilities and the Marriott's Bridges Program. In addition, ODE participated in several other recruiting fairs including: the FDA's 2003 Presidential Management Intern Job Fair; 2003 FDA Science Forum Job Fair; and the Department's Emerging Leaders Program, just to name a few.

Other Than Hiring to Expand/Enhance Resources Program (OTHER)

In an effort to enhance and expand resources for the Office of Device Evaluation, the Program Management Office continues to use a variety of methods through the OTHER initiative. Some of the OTHER programs that were utilized in FY 2003 include:

ORISE – Oak Ridge Institute for Science and Education –provides educational appointments for students, faculty, teachers, and post graduates at various FDA-approved host facilities; *ODE Employee Exchange* – useful for bringing employees from other FDA and CDRH offices into ODE for short periods; *Experts/Consultants* - intermittent temporary services of highly qualified people who possess unique professional, scientific, or technical expertise that is not available within the regular workforce; *Contracts* - arrangements that can be used to acquire services not available in the existing workforce and for short-term needs that require specific skills; *ODE Intern Program* - a no-cost program that brings students and professionals to ODE for short-term work experience; *ODE Employee Share Program* - an employee from one division works part-time or full-time for a limited period of time in another division within ODE or at another Office within the Center; *ODE University Partnership Program (UPP)* - partnership with medical schools to allow their students an opportunity to observe and learn the FDA medical device product approval process while assisting reviewers.

Training

ODE employees attended many courses, lectures, and grand rounds sponsored by the CDRH Staff College. They also attended local colleges and various off-site training institutions, and availed themselves of a multitude of other training opportunities associated within their field of expertise (e.g., meetings, seminars, workshops). ODE employees averaged 138 hours of training per employee in 2003. Supervisors continued to participate in monthly meetings to discuss current management issues, and all employees attended all-hands meetings to learn about new program polices and procedures.

Computer Tracking Systems

Significant work was done to the document tracking systems for the 510k, PMA, and Modular PMA data bases. New hold statuses were created and the data entry programs were modified to check MDUFMA payment status and to apply holds automatically. MDUFMA payment data was linked to the 510k, PMA, and PMR data entry programs and new programs were written to notify CDRH staff of payments received. A new flag was added to the 510k and PMA tracking systems for the STED Initiative. The Sted Initiative is a pilot program to assess the feasibility of using an internationally harmonized format in the review of certain submissions for device safety and performance.

Office Automation

ODE and OIVD continued to improve their desktop computer equipment with the installation of new desktop computers, and the upgrade of all desktop computer operating systems to Windows 2000 professional. ODE and OIVD prepared its staff to meet the FDA secure remote access requirements by providing training and equipment for offsite access to the FDA network.

A joint ODE/OIVD team worked with other Center employees involved in the PMA review process to develop procedures for an electronic shared workplace that will make the PMA review process more efficient. This will be done using web-based software that enables distributed teams to work together. It is hoped that this tool will facilitate collaborative review by increasing information dissemination among team members and will assist in fostering best business practices.

Electronic Submissions

In FY 03, ODE received 97 complete electronic copies of submissions for PMAs, IDEs, and 510(k)s from 25 different sponsors in addition to the paper submission. These numbers show an increase from FY 02 when 73 complete submissions were received from 14 different sponsors. Prior contact with an ODE or OIVD division is still requested before developing and sending an electronic copy. Electronic copies enhance the

efficiency of the review process, especially when several CDRH offices are involved in the review of the submission. Instructions for submitting submissions in electronic form can be found on the CDRH home page at the address http://www.fda.gov/cdrh/elecsub.html.

Video Conferencing

CDRH has the ability to conduct Room and Desktop Video Conferences with outside parties that have H.320 compliant systems, a standard for video conferencing over ISDN lines and other narrowband transmission media. In FY 03, ODE held 8 video conferences were held involving industry and other Federal agencies.

Medical Device Web Home Page

ODE and OIVD continue to provide information on the web that can be downloaded and searched through the ODE home page at http://www.fda.gov/cdrh/ode/and through the OIVD home page at http://www.fda.gov/cdrh/oivd/. Information on Premarket Approval Applications (PMAs) and Premarket Notifications (510(k)s) can be found on the ODE home page. Information about recent device approvals in ODE and OIVD can be found on the ODE home page under Medical Device Approvals and on the OIVD home page under All Cleared/Approved OIVD Products.

Image2000

The CDRH system for storing copies of past device application submissions was upgraded to provide additional capabilities for ODE/OIVD reviewers. Reviewer input played a major role in the redesign of the document repository and the upgraded system has been well-received. The system now stores documents in PDF format and allows for full text searching, for copying or saving documents and for printing all or part of the submission.

Consumer Information

The Consumer Staff in FDA's Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance (DSMICA) also provides information to consumers regarding medical devices and radiation-emitting products to enhance users ability to avoid risk, achieve maximum benefit, and make informed decisions about the use of such products.

Website: http://www.fda.gov/cdrh/consumer/index.html
E-Mail: dsmica@cdrh.fda.gov
Phone: Toll Free 1-888-463-6332 or 301-827-3990 directly between the hours of 8:00 a.m. – 4:30 p.m. EST
Fax: 301-443-9535

Part 7 – Operational Statistics

[NOTE: Although accurate at the time of publication, the data in the following tables may change slightly in subsequent reports to reflect changes in the regulatory status of submissions or verification of data entry. For example, if an incoming PMA supplement is later converted to an original PMA, changes are made in the appropriate tables. Likewise, some data from earlier reporting periods may have been changed to reflect similar corrections in data entry. These adjustments are not likely to have a significant effect on conclusions based on these data. Percentages of actions are presented in some tables. They may not add up to 100% in all cases due to the rounding off of fractions.] Refer to Tables 1 (page 14) and 2 (page 15) for general summary of major submissions received and completed.

Table 3. PMA/HDE/IDE/510(k) Submissions Received FY 99 - FY 03

TYPE OF SUBMISSION	NUMBER RECEIVED				
	FY99	FY00	FY01	FY02	FY03
Premarket Approval (PMAs)					
Original Applications	64	67	71	49	54
Amendments	743	975	746	748	564
Supplements	557	546	641	645	669
Amendments to Supplements	954	933	920	860	817
Reports for Original Applications	423	420	494	583	703
Reports for Supplements	0	0	0	1	0
Master Files	69	45	37	44	44
PMA Subtotal	**2,810**	**2,986**	**2,909**	**2,930**	**2,851**
Humanitarian Device Exemptions (HDEs)					
Original Applications	12	11	5	5	10
Amendments	55	56	62	53	41
Supplements	4	10	16	16	29
Amendments to Supplements	3	12	8	20	25
Reports for Original Applications	6	9	24	29	37
Reports for Supplements	0	0	0	0	0
HDE Subtotal	**80**	**98**	**115**	**93**	**142**
Investigational Device Exemptions (IDEs)					
Original Applications	304	311	284	312	242
Amendments	275	240	206	252	216
Supplements	4,127	4,388	4,811	4,724	4,414
IDE Subtotal	**4,706**	**4,939**	**5,301**	**5,288**	**4,872**
Premarket Notification (510(k)s)					
Original Notifications	4,458	4,202	4,248	4,320	4,247
Supplements	1,872	1,742	1,579	1,780	1,856
Amendments	2,962	2,953	2,620	2,385	1,690
510(k) Subtotal	**9,292**	**8,897**	**8,447**	**8,485**	**7,793**
PMA/HDE/IDE/510(k) Total	**16,812**	**16,919**	**16,772**	**16,796**	**15,658**

Table 4. Original PMA Decision Cohort Performance FY 99- FY 03

	FY 99	FY 00	FY 01	FY 02	FY03
Number Received	64	67	71	49	54
PMA Action					
Filing Decisions					
Filed	55	64	62	44	43
Not Filed	6	4	5	3	11
Others	0	0	0	0	0
Filing Decisions Subtotal	**61**	**68**	**67**	**47**	**54**
Scientific Review Decisions					
Major Deficiencies	27	51	35	29	29
Minor Deficiencies	4	11	4	2	1
Other[a]	126	111	95	91	57
Scientific Review Decisions Subtotal	**157**	**173**	**134**	**122**	**87**
Approval Decisions					
Approvals	36	42	53	41	31
Approvable	10	33	18	17	16
Not Approvable	1	4	10	10	10
Denials	0	0	0	0	0
Approval Decision Subtotal	**47**	**79**	**81**	**68**	**57**
Total PMA Actions	**266**	**320**	**282**	**237**	**198**
Average Review Time (Days) for Approvals[b]					
FDA	153	173	129	161	151
Non-FDA	26	41	43	52	70
Total	**179**	**214**	**172**	**213**	**221**
Average Elapsed Time (Days) for Approvals[c]					
FDA	313	254	257	260	246
Non-FDA	115	114	154	104	113
Total	**428**	**368**	**411**	**364**	**359**
Number under Review at End of Period[d]					
Active[e]	74	52	53	42	35
(Active and Overdue)	(33)	(17)	(13)	(7)	(2)
On Hold[f]	40	39	39	31	48
Total	**114**	**91**	**92**	**73**	**83**

a/ Includes actions that did not result in an approval/denial decision, such as GMP deficiency letters prior to inspection, an applicant directed hold, reclassification of the device and conversion of the PMA to another regulatory category, or official correspondence concerning abandonment or withdrawal of the PMA, placing the PMA on hold, and other miscellaneous administrative actions.

b/ Average review times are calculated under the Premarket Approval of Medical Devices Regulation *(21 CFR Part 814)*. Under this regulation, the review clock is *reset* upon FDA's receipt of a "major amendment" or a response to a "refuse to file" letter. Thus, average review time, unlike average elapsed time, *excludes* all review times that occurred prior to the latest resetting of the clock.

c/ The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus the average elapsed time is the average time taken to obtain approval of a PMA from its filing date until it receives final approval.

d/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions not reflected in the table.

e/ FDA responsible for processing application.

f/ FDA processing of applications officially suspended pending receipt of additional information from the applicant.

Table 5. Original PMA Receipt Cohort Performance*
FY 99– FY 03

	FY99	FY00	FY01	FY02	FY03
Original PMAs Filed					
PMAs	48	60	58	32	16
Expedited PMAs	7	8	9	9	1
Total	**55**	**68**	**67**	**41**	**17**
Filing Decisions[a]					
Filed	55	68	67	41	17
Not Filed	1	3	3	0	2
Number (%) of Filing/Not Filing Decisions within 45 Days	44(79)	54(76)	47(66)	31(76)	13(68)
Average Days/Cycle	42	41	44	41	37
Final Actions[b]					
Approvals	52	45	45	25	4
Denials	0	0	0	0	0
Other[c]	12	22	14	8	1
Total	**64**	**67**	**59**	**33**	**5**
Filing to First Action Excluding withdrawals, conversions, etc.[d]					
Number Received and Filed	55	68	67	41	17
Number of First Actions	55	63	67	41	17
Average FDA Days	145	132	132	136	144
Median FDA Days	147	143	133	143	158
Number (%) of First Actions with 180 Days	43(78)	63(100)	65(97)	38(93)	16(94)
Filing to First Action Including withdrawals, conversions, etc.[e]					
Number Received and Filed	55	68	67	41	17
Number of First Actions	55	68	67	41	17
Average FDA Days	145	133	132	136	144
Median FDA Days	147	136	133	143	158
Number (%) of First Actions with 180 Days	43(78)	68(100)	65(97)	38(93)	16(94)
Filing to Final Action Excluding withdrawals, conversions, etc.[f]					
Number Received and Filed	55	68	67	41	17
Number of Final Actions	49	47	46	25	4
Average FDA (Total) Elapsed Time	277(394)	225(342)	232(291)	235(313)	193(215)
Median FDA (Total) Elapsed Time	251(354)	181(280)	191(251)	198(300)	174(218)
Number (%) of Final Actions with 180 FDA Days	8(16)	22(47)	19(41)	11(44)	3(75)
Number (%) of Final Actions with 180 Total Days	5(10)	7(15)	11(24)	4(16)	2(50)
Filing to Final Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	55	68	67	41	17
Number of Final Actions	55	68	55	28	4
Average FDA (Total) Elapsed Time	274(424)	210(376)	221(318)	238(328)	193(215)
Median FDA (Total) Elapsed Time	252(372)	179(299)	182(275)	217(315)	174(218)
Number (%) of Final Actions with 180 FDA Days	10(18)	40(59)	25(45)	12(43)	3(75)
Number (%) of Final Actions with 180 Total Days	5(9)	12(18)	11(20)	4(14)	2(50)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[b]	2.1	1.6	1.6	1.8	1.0

(Continued on next page.)

Table 5. Original PMA Receipt Cohort Performance*
FY 99 - FY 03

(Continued from previous page.)

	FY99	FY00	FY01	FY02	FY03
Percentile FDA Days from Filing to First Action[d]					
25th	115	99	105	108	121
50th (Median)	147	143	133	143	158
75th	179	177	176	176	176
90th	227	180	179	180	178
Percentile FDA Days from Filing to First Action[e]					
25th	115	99	105	108	121
50th (Median)	147	136	133	143	158
75th	179	175	176	176	176
90th	227	179	179	180	178
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	207(253)	175(205)	177(180)	178(234)	164(166)
50th (Median)	251(354)	181(280)	191(251)	198(300)	174(218)
75th	330(491)	286(440)	271(329)	282(392)	222(264)
90th	405(660)	342(534)	358(469)	341(435)	268(268)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	201(254)	168(204)	171(196)	178(252)	164(166)
50th (Median)	252(372)	179(299)	182(275)	217(315)	174(218)
75th	327(587)	277(486)	261(403)	283(417)	222(264)
90th	404(757)	341(782)	335(536)	374(451)	268(268)
Active	0	0	2	4	5
(Active and Overdue)	0	0	0	0	0
On Hold[h]	0	0	10	12	12
Total	**0**	**0**	**12**	**16**	**17**
Summary of PMA Receipt Cohort					
Approved	52	45	45	25	4
Denied	0	0	0	0	0
Withdrawn	6	17	12	6	1
Other	6	5	2	2	0
Under Review	0	0	2	4	5
On Hold[h]	0	0	10	12	12
Total	**64**	**67**	**71**	**49**	**22**

/ For each fiscal year, September 30, 2003 was used as the cutoff date. The FY03 cohort represents only receipts through March 31, 2003 (first 6 months of the fiscal year). The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus the average elapsed time is the average time taken to obtain approval of a PMA from its filing date until it receives final approval.

(Continued on next page.)

Table 5. Original PMA Receipt Cohort Performance
FY 99 – FY 03

(Continued from previous page.)

a/ The filing decision represents the count of applications with a filing date within the fiscal year as of the cutoff date. For example, a PMA that is considered complete at the time of submission would have a received date equal to the filed date. However, if the agendy refuses to file the PMA, it is considered incomplete and the filed date becomes the date of the amendment that makes the submission complete for filing. Therefore, it is possible that the submission may be received in one fiscal year but not be considered a filed PMA until a subsequent fiscal year. For the purpose of receipt cohort reporting, PMAs are considered "received" based on the filing date rather than the receipt date.

b/ The final action analyses include actions as of the cutoff date for PMAs received within the fiscal year.

c/ Includes only actions that resulted in withdrawal, conversion, and other final action not resulting in approval or denial.

d/ The first action analyses include actions as of the cutoff date for PMAs that were filed within the fiscal year. This measure excludes PMAs with a final action of withdrawal, conversion, or other final actions.

e/ The first action analyses include actions as of the cutoff date for PMAs that were filed within the fiscal year. This measure includes PMAs with any final action including approval, denial, withdrawal, conversion, or other final actions.

f/ The final actions analyses include actions as of the cutoff date for PMAs that were filed within the fiscal year. This measure excludes PMAs with a final action of withdrawal, conversion, or other final action not resulting in approval or denial.

g/ The final actions analyses include actions as of the cutoff date for PMAs that were filed within the fiscal year. This measure includes PMAs with any final action including approval, denial, withdrawal, conversion, or other final actions.

h/ "On Hold" describes the FDA processing of applications officially suspended pending receipt of additional information from the applicant.

Table 6. PMA Supplement Decision Cohort Performance FY 99 - FY 03

	FY99	FY00	FY01	FY02	FY03
Number Received	557	546	641	645	669
PMA Supplement Actions					
Panel Track Filing Decisions[a]					
Filed	17	15	11	24	5
Not Filed	2	3	4	1	1
Other	0	0	0	0	0
Filing Decision Subtotal	**19**	**18**	**15**	**25**	**6**
Scientific Review Decisions					
Major Deficiencies	12	13	9	12	6
Minor Deficiencies	0	1	0	0	1
Other[b]	76	83	78	93	91
Scientific Review Decisions Subtotal	**88**	**97**	**87**	**105**	**98**
Approval Decisions					
Panel Track Approvals[c]	11	11	11	16	11
Nonpanel Track Approvals	429	463	431	517	483
Approvable	95	100	100	102	94
Not Approvable	62	59	52	51	47
Approval Decision Subtotal	**597**	**633**	**594**	**686**	**635**
Total PMA Supplement Actions	**704**	**748**	**696**	**816**	**739**
Average Review Time (Days) for Approvals[d]					
FDA	76	76	71	85	72
Non-FDA	18	18	26	20	21
Total	**94**	**94**	**97**	**105**	**93**
Average Elapsed Time (Days) for Approvals[e]					
FDA	92	95	78	96	85
Non-FDA	27	26	32	28	26
Total	**119**	**121**	**110**	**124**	**111**
Number Under Review at End of Period[f]					
Active[g]	157	100	155	127	123
(Active and Overdue)	(3)	(2)	(9)	(2)	(4)
On Hold[h]	65	82	94	97	111
Total	**222**	**182**	**249**	**224**	**234**

a/ Filing and not filing decisions are for panel track PMA supplements only. Nonpanel track PMA supplements are automatically filed upon receipt.

b/ Includes actions that did not result in an approval/denial decision, such as GMP letters prior to inspection, an applicant directed hold, reclassification of the device and conversion of the PMA supplement to another regulatory category, and official correspondence concerning the abandonment or withdrawal fo the supplement, the status of the supplement as a special (change being effected) or 30-day submission, and other miscellaneous administrative action.

(Continued on next page.)

Table 6. PMA Supplement Decision Cohort Performance FY 99 - FY 03

(Continued from previous page.)

c/ Panel track supplements are subject to the full administrative procedures normally associated with original PMAs, i.e., panel review, preparation of a summary of safety and effectiveness.

d/ Average review times are calculated under the Premarket Approval of Medical Devices Regulation (21 *CFR* Part 814). Under this regulation, the review clock is *reset* upon FDA's receipt of a "major amendment" or a response to a "refuse to file" letter. Thus, average review time, unlike average elapsed time, *excludes* all review times that occurred prior to the latest resetting of the clock.

e/ The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, furing which time it was being worked on by the manufacturer. Thus the average elapsed time is the average time takento obtain approval of a PMA from its filing date until it receives final approval.

f/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

g/ FDA responsible for processing application.

h/ FDA processing of applications officially suspended pending receipt of additional information from the applicant.

Table 7. PMA Supplement Receipt Cohort Performance*
FY 99 - FY 03

	FY99	FY00	FY01	FY02	FY03
PMA Supplements Filed					
PMA Supplements	530	533	623	625	363
Expedited PMA Supplements	2	1	0	0	0
Total	**532**	**534**	**623**	**625**	**363**
PMA Supplement Final Actions [a]					
Approvals	442	422	470	488	250
Denials	0	0	0	0	0
Other[b]	92	103	138	104	86
Filing to First Action Excluding withdrawals, conversions, etc.[c,d]					
Number Received and Filed	532	534	623	625	363
Number of First Actions	513	517	602	604	342
Average FDA Days	72	63	71	72	61
Median FDA Days	36	37	36	36	32
Number (%) of First Actions within 180 Days	464(90)	505(98)	569(95)	583(97)	338(99)
Filing First Action Including withdrawals, conversions, etc.[e]					
Number Received and Filed	532	534	623	625	363
Number of First Actions	532	534	620	625	358
Average FDA Days	73	64	71	73	60
Median FDA Days	35	35	35	36	30
Number (%) of First Actions within 180 Days	481(90)	521(98)	586(95)	599(96)	354(99)
Filing to Final Action Excluding withdrawals, conversions, etc.[f]					
Number Received and Filed	532	534	623	625	363
Number of First Actions	488	493	579	564	317
Average FDA (Total) Review Days	77(107)	69(93)	78(97)	74(89)	57(67)
Median FDA (Total) Review Days	34(47)	33(42)	33(43)	35(43)	30(36)
Number (%) of Final Actions within 180 Days	424(87)	465(94)	520(90)	521(92)	310(98)
Number (%) of Final Actions within 180 Total Days	402(82)	437(88)	490(85)	500(89)	305(96)
Filing to Final Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	532	534	623	625	363
Number of First Actions	529	525	607	592	334
Average FDA (Total) Review Days	85(129)	69(103)	78(100)	76(92)	56(68)
Median FDA (Total) Review Days	36(55)	35(43)	34(43)	35(46)	30(39)
Number (%) of Final Actions within 180 Days	455(86)	493(94)	545(90)	544(92)	327(98)
Number (%) of Final Actions within 180 Total Days	420(79)	454(86)	509(84)	516(87)	319(96)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[a]	1.1	1.1	1.1	1.0	1.0

Table 7. PMA Supplement Receipt Cohort Performance*
FY 99 - FY 03

(Continued from previous page.)

	FY99	FY00	FY01	FY02	FY03
Percentile FDA Days from Filing to First Action[d]					
25th	19	21	25	20	23
50th (Median)	36	37	36	36	32
75th	147	113	127	137	117
90th	189	176	180	179	179
Percentile FDA Days from Filing to First Action[e]					
25th	19	20	24	20	22
50th (Median)	35	35	35	36	30
75th	135	109	120	130	99
90th	180	165	178	177	174
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	18(24)	19(25)	24(27)	20(27)	22(27)
50th (Median)	34(47)	33(42)	33(43)	35(43)	30(36)
75th	138(154)	106(127)	124(151)	132(152)	75(97)
90th	190(236)	176(195)	181(209)	179(196)	160(171)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	19(25)	20(25)	23(27)	20(27)	22(27)
50th (Median)	36(55)	35(43)	34(43)	35(46)	30(39)
75th	146(168)	110(141)	126(156)	133(159)	75(95)
90th	196(280)	176(217)	181(223)	179(212)	153(172)
Number Pending as of 9/30/01					
Active	0	0	1	5	8
(Active and Overdue)	0	0	0	0	(4)
On Hold[h]	3	9	15	28	21
Total	**3**	**9**	**16**	**33**	**29**
Summary of PMA Supplement Receipt Cohort					
Approved	442	422	470	488	250
Denied	0	0	0	0	0
Withdrawn	38	26	27	24	17
Other	54	77	111	80	69
Under Review	0	0	1	5	8
On Hold[h]	3	9	15	28	21
Total	**537**	**534**	**624**	**625**	**365**

***/** For each fiscal year, September 30, 2003 was used as the cutoff date. The FY03 cohort represents only receipts through March 31, 2003 (first 6 months of the fiscal year). The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus the average elapsed time is the average time taken to obtain approval of a PMA from its filing date until it receives final approval. Panel Track Supplement times are quantified in Table 8.

(Continued on next page.)

Table 7. PMA Supplement Receipt Cohort Performance*
FY 99 - FY 03

(Continued from previous page.)

a/ The final action analyses include actions as of the cutoff date for PMA supplements received within the fiscal year.

b/ Includes only actions that resulted in withdrawal, conversion, and other final action not resulting in approval or denial.

c/ Filing and not filing decisions are for panel track PMA supplements only. Nonpanel track PMA supplements are automatically filed upon receipt.

d/ The first action analyses includes actions as of the cutoff date for PMAs that were filed within the fiscal year. This measure excludes PMA supplements with a final action of withdrawal, conversion, or other final actions.

e/ The first action analyses include actions as of the cutoff date for PMA supplements that were filed within the fiscal year. This measure includes PMA supplements with any final action including approval, denial, withdrawal, conversion, or other final actions.

f/ The final actions analyses include actions as of the cutoff date for PMA supplements that were filed within the fiscal year. This measure excludes PMA supplements with a final action of withdrawal, conversion, or other final action not resulting in approval or denial.

g/ The final actions analyses include actions as of the cutoff date for PMA supplements that were filed within the fiscal year. This measure includes PMA supplements with any final action including approval, denial, withdrawal, conversion, or other final actions.

h/ "On Hold" describes the FDA processing of applications officially suspended pending receipt of additional information from the applicant.

Table 8. PMA Panel Track Supplement Receipt Cohort Performance*
FY 99 – FY 03

	FY99	FY00	FY01	FY02	FY03
PMA Panel Track Supplements Filed					
Panel Track PMA Supplements	11	8	13	17	3
Expedited Panel Track PMA Supplements	4	3	1	3	1
Total	**15**	**11**	**14**	**20**	**4**
Filing Decisions [a]					
Filed	15	11	14	20	4
Not Filed	0	1	2	1	1
Number of Filing/Not Filing Decisions with 45 Days	10	10	14	15	4
Average Days/Cycle	45	39	38	47	35
PMA Panel Track Supplement Final Actions [b]					
Approvals	14	6	12	17	1
Denials	0	0	0	0	0
Other [c]	4	4	3	0	1
Filing to First Action Excluding withdrawals, conversions, etc. [d]					
Number Received and Filed	15	11	14	20	4
Number of First Actions	15	11	14	20	4
Average FDA Days	134	119	136	144	113
Median FDA Days	162	135	135	158	107
Number (%) of First Actions within 180 Days	13(87)	10(91)	13(93)	18(90)	4(100)
Filing First Action Including withdrawals, conversions, etc. [e]					
Number Received and Filed	15	11	14	20	4
Number of First Actions	15	11	14	20	4
Average FDA Days	134	119	136	144	113
Median FDA Days	162	135	135	158	107
Number (%) of First Actions within 180 Days	13(87)	10(91)	13(93)	18(90)	4(100)
Filing to Final Action Excluding withdrawals, conversions, etc. [f]					
Number Received and Filed	15	11	14	20	4
Number of First Actions	13	6	11	17	1
Average FDA (Total) Review Days	274(327)	214(231)	241(319)	230(292)	234(234)
Median FDA (Total) Review Days	199(252)	214(248)	221(276)	200(226)	234(234)
Number (%) of Final Actions within 180 Days	5(38)	2(33)	5(45)	6(35)	0(0)
Number (%) of Final Actions within 180 Total Days	4(31)	2(33)	4(36)	3(18)	0(0)
Filing to Final Action Including withdrawals, conversions, etc. [g]					
Number Received and Filed	15	11	14	20	4
Number of First Actions	14	10	13	17	1
Average FDA (Total) Review Days	272(321)	255(363)	244(341)	230(292)	234(234)
Median FDA (Total) Review Days	217(244)	226(304)	221(276)	200(226)	234(234)
Number (%) of Final Actions within 180 Days	6(43)	3(30)	6(46)	6(35)	0(0)
Number (%) of Final Actions within 180 Total Days	4(29)	2(20)	4(31)	3(18)	0(0)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc. [b]	2.0	1.8	1.8	1.6	3.0

(Continued on next page.)

Table 8. PMA Panel Track Supplement Receipt Cohort Performance*
FY 99 – FY 03

(Continued from previous page.)

	FY99	FY00	FY01	FY02	FY03
Percentile FDA Days from Filing to First Action[d]					
25th	84	88	81	119	99
50th (Median)	162	135	135	158	107
75th	179	157	174	174	127
90th	185	175	180	191	145
Percentile FDA Days from Filing to First Action[e]					
25th	84	88	81	119	99
50th (Median)	162	135	135	158	107
75th	179	157	174	174	127
90th	185	175	180	191	145
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	179(179)	144(144)	174(174)	171(216)	234(234)
50th (Median)	199(252)	214(248)	221(276)	200(226)	234(234)
75th	385(385)	266(295)	288(539)	216(415)	234(234)
90th	450(494)	313(313)	313(555)	385(494)	234(234)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	179(179)	144(209)	175(175)	171(216)	234(234)
50th (Median)	217(244)	226(304)	221(276)	200(226)	234(234)
75th	385(385)	313(510)	288(539)	216(415)	234(234)
90th	450(494)	451(709)	343(664)	385(494)	234(234)
Number Pending as of 9/30/02					
Active	0	1	0	0	2
(Active and Overdue)	0	0	0	0	0
On Hold[h]	2	1	2	3	0
Total	**2**	**2**	**2**	**3**	**2**
Summary of PMA Supplement Receipt Cohort					
Approved	14	6	12	17	1
Denied	0	0	0	0	0
Withdrawn	4	4	3	0	1
Other	0	0	0	0	0
Under Review	0	1	0	0	2
On Hold[h]	2	1	2	3	0
Total	**20**	**12**	**17**	**20**	**4**

***/** For each fiscal year, September 30, 2003 was used as the cutoff date. The FY03 cohort represents only receipts through March 31, 2003 (first 6 months of the fiscal year). The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus the average elapsed time is the average time taken to obtain approval of a PMA from its filing date until it receives final approval.

(Continued on next page.)

Table 8. PMA Panel Track Supplement Receipt Cohort Performance*
FY 99 – FY 03

(Continued from previous page.)

a/ Filing and not filing decisions are for panel track PMA supplements only. Nonpanel track PMA supplements are automatically filed upon receipt.

b/ The final action analyses include actions as of the cutoff date for PMA supplements received within the fiscal year.

c/ Includes only actions that resulted in withdrawal, conversion, and other final action not resulting in approval or denial.

d/ The first action analyses include actions as of the cutoff date for PMA supplements that were filed within the fiscal year. This measure excludes PMA supplements with a final action of withdrawal, conversion, or other final actions.

e/ The first action analyses include actions as of the cutoff date for PMA supplements that were filed within the fiscal year. This measure includes PMA supplements with any final action including approval, denial, withdrawal, conversion, or other final actions.

f/ The final actions analyses include actions as of the cutoff date for PMA supplements that were filed within the fiscal year. This measure excludes PMA supplements with a final action of withdrawal, conversion, or other final action not resulting in approval or denial.

g/ The final actions analyses include actions as of the cutoff date for PMA supplements that were filed within the fiscal year. This measure includes PMA supplements with any final action including approval, denial, withdrawal, conversion, or other final actions.

h/ "On Hold" describes the FDA processing of applications officially suspended pending receipt of additional information from the applicant.

Table 9. HDE Submissions Received
FY 99 – FY 03

TYPE OF SUBMISSION	NUMBER RECEIVED				
	FY99	FY00	FY01	FY02	FY03
Humanitarian Device Exemptions (HDEs)					
Original Applications	12	11	5	5	10
Amendments	55	56	62	54	41
Supplements	4	10	16	16	29
Amendments to Supplements	3	12	8	20	25
Reports for Original Applications	6	9	24	29	37
Reports for Supplements	0	0	0	0	0
Total	**80**	**98**	**115**	**124**	**142**

Table 10. Original HDE Decision Cohort Performance

FY 99 – FY 03

	FY 99	FY 00	FY 01	FY 02	FY03
Number Received	12	11	5	5	10
HDE Action					
Filing Decisions					
Filed	10	8	6	6	6
Not Filed	1	4	1	1	5
Others[a]	1	0	0	0	2
Filing Decisions Subtotal	**12**	**12**	**7**	**7**	**13**
Scientific Review Decisions					
Major Deficiencies	6	7	7	6	4
Minor Deficiencies	0	3	6	2	3
Other[b]	4	6	2	0	2
Scientific Review Decisions Subtotals	**10**	**16**	**15**	**8**	**9**
Approval Decisions					
Approvals	6	6	4	6	2
Approvable	5	1	0	0	0
Not Approvable	0	0	0	0	0
Denials	0	0	0	0	0
Approved Decision Subtotal	**11**	**7**	**4**	**6**	**2**
Other Final Decisions[c]	4	1	4	2	2
Total HDE Actions	**37**	**36**	**30**	**23**	**26**
Filing to First Action[d]					
Number of First Actions	13	8	6	6	3
Average Number of FDA Days	87	61	42	53	48
Number of First Actions Within 75 Days	7	8	6	5	2
Average Elapsed Time (Days) for Approvals[e]					
FDA	113	112	143	175	152
Non-FDA	50	104	100	127	96
Total	**163**	**216**	**243**	**302**	**248**
Average Number of FDA Cycles from Receipt to Final Action[f]	1.2	1.3	1.9	2.1	2.0
Number under Review at End of Period[g]					
Active[h]	2	2	1	1	4
Active and Overdue	0	0	0	0	0
On Hold[i]	8	8	6	3	6
Total	**10**	**10**	**7**	**4**	**10**

a/ Includes interim action, placing a file on hold, such as jurisdiction issue, and final actions, such as withdrawal or conversion to another regulatory category, that occur prior to a filing decision being made.

b/ Includes actions that did not result in a final decision, such as GMP deficiency letter or an applicant-directed hold.

c/ Includes final actions other than approval or denial, such as withdrawal, abandonment warning letter or conversions to another regulatory category.

(Continued on next page.)

Table 10. Original HDE Decision Cohort Performance

FY 99 – FY 03

(Continued from previous page.)

d/ First actions may include major and minor deficiency decisions; approvable, not approvable, approval and denial decisions; receipt of an unsolicted major amendment; and other final actions, such as withdrawal or conversion to another regulatory category.

e/ The average amount of time taken to obtain approval of an HDE from the filing date until final approval.

f/ A cycle is counted as the intial submission and each resetting of FDA's review clock, such as a response to a non-filing decision or the submission of a major amendment.

g/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions not reflected in the table.

h/ The application is under review by FDA.

i/ FDA's review of the application is officially suspended pending receipt of additional information from the applicant.

Table 11. HDE Supplement Decision Cohort Performance FY 99 – FY 03

	FY99	FY00	FY01	FY02	FY03
Number Received	4	10	16	16	29
HDE Supplement Actions					
Scientific Review Decisions					
Major Deficiencies	1	0	0	0	0
Minor Deficiencies	0	0	0	0	1
Other[a]	2	0	1	1	3
Scientific Review Decisions Subtotal	**3**	**0**	**1**	**1**	**4**
Approval Decisions					
Approvals	3	10	11	13	24
Approvable	1	0	0	6	5
Not Approvable	0	1	1	6	6
Denials	0	0	0	0	0
Approval Decision Subtotal	**4**	**11**	**12**	**25**	**35**
Other Final Decisions[b]	0	0	1	1	2
Total HDE Actions	**7**	**11**	**13**	**27**	**37**
Filing to First Action[c]					
Number of First Actions	4	10	12	17	29
Average Number of FDA Days	57	44	52	53	37
Number of First Actions within 75 Days	4	10	8	16	26
Average Elapsed Time (Days) for Approvals[d]					
FDA	70	43	46	60	43
Non-FDA	24	33	0	14	52
Total	**94**	**76**	**46**	**74**	**95**
Average Number of FDA Cycles from Receipt to Final Action[e]	1.3	1.0	1.0	1.3	1.0
Number Under Review at End of Period[f]					
Active[g]	0	0	4	4	5
(Active and Overdue)	0	0	0	0	0
On Hold[h]	1	1	1	4	6
Total	**1**	**1**	**5**	**8**	**11**

a/ Includes actons that did not result in a final decision, such as GMP deficiency letter, an applicant-directed hold, official correspondence concerning the status of the supplement or other miscellaneous administrative action.

b/ Includes final actions other than approval or denial, such as withdrawal or conversion to another regulatory category.

(Continued on next page.)

Table 11. HDE Supplement Decision Cohort Performance FY 99 – FY 03

(Continued from previous page.)

c/ First actions may include major and minor deficiency decisions; approvable, not approvable, approval and denial decisions; receipt of an unsolicited major amendment; and other final actions, such as withdrawal or conversion to another regulatory category.

d/ The average amount of time taken to obtain approval of an HDE Supplement from the filing date until final approval.

e/ A cycle is counted as the initial submission and each resetting of FDA's review clock, such as a response to a non-filing decision or the submission of a major amendment.

f/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

g/ The application is under review by FDA.

h/ FDA 's review of the application is officially suspended pending receipt of additional information from the applicant.

Table 12. Original IDEs
FY 99 - FY 03

	FY99	FY00	FY01	FY02	FY03
Number Received	304	311	284	312	242
Number of Decisions					
Approved	176	213	208	209	146
Not Approved	82	66	53	75	78
Other[a]	47	41	23	23	22
Total	**305**	**320**	**284**	**307**	**246**
Percent (%) of Approvals Made during First Review Cycle[b]	68	76	80	74	65
Average FDA Review Time (days)	27	28	28	28	27
Percent (%) of Decisions Made within 30 Days	99	99	100	99	100
Number under Review at End of Period[c]	28	19	18	22	18
Number Overdue at End of Period	0	0	0	0	0

a/ Includes deletions, withdrawals, and other administrative actions not resulting in an approval/disapproval decision.

b/ Based on "approved" and "not approved" decisions only.

c/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts lessapprovals) because of deletions and conversions which are not reflected in the table.

Table 13. IDE Amendments
FY 99 - FY 03

	FY99	FY00	FY01	FY02	FY03
Amendments Received[a]	275	240	206	252	216
Decisions on Amendments					
Approved	97	107	73	86	73
Not Approved	42	34	39	55	40
Other[b]	129	110	95	110	104
Total	**268**	**251**	**207**	**251**	**217**
Average FDA Review Time (days)	18	19	18	18	19
Percent (%) of Decisions Made within 30 Days	100	100	99	100	100
Average Approval Time (days) For IDEs with Amendments					
FDA Time	57	70	59	68	68
Non-FDA Time	88	66	82	67	112
Total Time[c]	**145**	**136**	**141**	**135**	**180**
Number of Amendments per Approved IDE	1.6	2.3	1.7	2.2	2.1
Amendments under Review at End of Period[d]	19	9	8	7	6
Amendments Overdue at End of Period	0	0	0	0	0

a/ Submissions received after the original IDE and prior to approval of the IDE application.

b/ Includes actions that did not result in an approval/disapproval decision, such as withdrawal of the IDE or the amendment by the sponsor, and other administrative actions, e.g., acknowledgement letters concerning the submission of information that did not require independent approval/disapproval and other administrative information, such as a change of address.

c/ The average IDE approval time represents the total time it has taken, on average, for an original IDE that was initially disapproved to be approved after the submission of amendments to correct deficiencies. The time being measured here covers the period from the date the original IDE was received to the date of final approval of an IDE amendment.

d/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

Table 14. IDE Supplements
FY 99 - FY 03

	FY99	FY00	FY01	FY02	FY03
Number Received	4,127	4,388	4,811	4,724	4,415
Number of Decisions	4,224	4,335	4,803	4,711	4,424
Average FDA Review Time (days)	20	20	21	20	19
Percent (%) OF Decisions Made within 30 Days	100	100	100	100	100
Number under Review at End of Period[a]	187	239	247	260	249
Number Overdue at End of Period	0	0	0	0	0

a/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

Table 15. 510(k) Decision Cohort Performance
FY 99 - FY 03

	FY99	FY00	FY01	FY02	FY03
Number Originals Received	4,458	4,202	4,248	4,320	4,247
Number of Decisions					
Substantially Equivalent	3,652	3,567	3,428	3,667	3,522
Not Substantially Equivalent	66	52	46	69	88
Other[a]	875	778	676	640	522
Total	**4,593**	**4,397**	**4,150**	**4,376**	**4,132**
Percent (%) Not Substantially Equivalent[b]	1.8	1.4	1.3	1.8	2.4
Average Review Time (Days)					
FDA Time[c]	80	77	75	79	76
Total Time[d]	102	102	96	100	96
Median Review Time (Days)					
FDA Time[c]	71	68	68	70	65
Total Time[d]	76	72	72	74	72
Percent(%) of Decisions made within 90 Days, based on					
FDA Time[e]	99	100	100	100	99
Total Time[d]	66	66	69	69	69
Number under Review at End of Period[f]					
Active[g]	943	850	934	935	1,015
(Active and Overdue)	0	0	0	0	0
On Hold[h]	461	370	382	337	376
Total	**1,404**	**1,220**	**1,316**	**1,272**	**1,391**

a/ Includes final administrative actions that did not result in a substantially equivalent/not substantially equivalent decision because of the 510(k) or device/product was withdrawn by the applicant, deleted due to lack of response, a duplicate, not a device, a transitional device, regulated by CBER, a general purpose article, exempted by regulation, and other miscellaneous action.

b/ Based on "substantially equivalent" and "not substantially equivalent" decisions only.

c/ FDA time includes all increments of time FDA reviewed a 510(k), so long as the 510(k) document number did not change; changes in 510(k) document numbers occur rarely.

d/ Includes all time from receipt to final decision, i.e., does not exclude time a submission is on hold pending receipt of additional information.

e/ Considers whether FDA review time remained within 90 days, with FDA's review clock being reset to zero whenever additonal information was received (in accordance with 21 *CFR* 807.87(l)).

f/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less decisions) because of deletions and conversions which are not reflected in the table.

g/ FDA responsible for processing notification.

h/ FDA's processing of notification officially suspended pending receipt of additional information from the submitter.

Table 16. 510(k) Receipt Cohort Performance*
FY 99 - FY 03

	FY99	FY00	FY01	FY02	FY03
Number of 510(k)s Received[a]					
Traditional	3,985	3,471	3,370	3,353	2,294
Special	396	584	710	785	605
Abbreviated	85	149	174	184	153
Total Receipts	**4,466**	**4,204**	**4,254**	**4,322**	**3,052**
Actions on 510(k)s					
Substantially Equivalent	3,605	3,423	3,574	3,566	2,261
Not Substantially Equivalent (%)[b]	63(1.7)	44(1.3)	61(1.7)	71(2)	45(2)
Other[c]	798	737	617	621	259
Total Actions	**4,466**	**4,204**	**4,252**	**4,258**	**2,565**
Average Cumulative Days for 510(k) Decisions					
Excludes Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	81	75	79	75	63
Total Time from Receipt to Final Decision[e]	104	95	99	91	72
All Decisions Including Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	79	74	78	74	61
Total Time from Receipt to Final Decision[e]	114	104	107	101	73
Number of Decisions (%) with 90 Days, Based on:					
FDA Days from Receipt to First Action	4,453(100)	4,198(100)	4,245(100)	4,311(100)	3,039(100)
FDA Cumulative Days from Receipt to Final Decisions	3,372(76)	3,370(80)	3,264(77)	3,377(78)	2,214(73)
Total Cumulative Days from Receipt to Final Decisions[e]	2,938(66)	2,916(69)	2,889(68)	3,018(70)	2,057(67)
Average Number of FDA Cycles from Receipt to Final Action	1.4	1.4	1.4	1.4	1.3
Percentile FDA (Total) Days from Receipt to Final Action					
25th	41(45)	35(41)	31(35)	30(34)	29(30)
50th (Median)	71(78)	65(73)	70(77)	69(76)	67(76)
75th	90(147)	89(126)	90(145)	90(130)	109(159)
90th	160(263)	153(238)	162(237)	162(252)	N/A(N/A)
Number under Review as of 9/30/01					
Active	0	0	2	17	224
Active and Overdue	0	0	0	0	0
On Hold	0	0	0	47	261
Total	**0**	**0**	**2**	**64**	**485**
Summary of 510(k) Receipt Cohort					
Substantially Equivalent	3,605	3,423	3,574	3,566	2,261
Not Substantially Equivalent	63	44	61	71	45
Other	798	737	617	621	259
Under Review	0	0	2	17	224
On Hold	0	0	0	47	261
Total	**4,466**	**4,204**	**4,254**	**4,322**	**3,052**

(Continued on next page.)

Table 16. 510(k) Receipt Cohort Performance*
FY 99 – FY 03

(Continued from previous page.)

***/** For each fiscal year, September 30, 2003 was used as the cutoff date. The FY03 cohort represents only receipts through June 30, 2003 (first nine months of the fiscal year).

a/ Includes Third Party 510(k)s: FY99 = 32; FY00 = 47; FY01 =107; FY02 = 127; FY03 = 126 (9 months)

b/ Based on "substantially equivalent" and "not substantially equivalent" decisions only.

c/ Includes final administrative actions that did not result in a substantially equivalent/not substantially equivalent decision because the 510(k) or device/product was: withdrawn by the applicant, deleted due to lack of response, a duplicate, not a device, a transitional device, regulated by CBER, a general purpose article, exempted by regulation, and other miscellaneous actions.

d/ FDA time includes all increments of time FDA reviewed a 510(k), so long as the 510(k) document number did not change; changes in 510(k) document numbers occur rarely.

e/ Includes all time from receipt to final decision, i.e., does not exclude time a submission is on hold pending receipt of additional information.

Appendix A – Summary of Major ODE/OIVD Programs

ODE and OIVD are responsible for the program areas through which medical devices are evaluated or cleared for clinical trials and marketing. This Appendix provides summary information about the major programs administered by ODE/OIVD and includes a brief description of the premarket approval, product development protocol, humanitarian device exemption, investigational device exemption, and premarket notification programs.

Premarket Approval Applications (PMAs)

Under the Federal Food, Drug, and Cosmetic Act (the Act) and the FDA regulations, *Code of Federal Regulations, Title 21* (the Regulations), a manufacturer or others must submit a PMA for FDA review and approval before marketing certain new Class III devices. The PMA submitter must provide reasonable assurance that the device is safe and effective for its intended use and that it will be manufactured in accordance with current good manufacturing practices. As part of the review process, FDA may present the PMA to an expert advisory panel for its recommendations. After obtaining the panel recommendations, the agency makes a determination to approve the PMA, deny it, or request additional information. When the FDA either approves or denies the PMA, it must publish a notice in the *Federal Register* to inform the public of the decision and make available a summary of the safety and effectiveness data upon which the decision is based. This publicly available summary does not include proprietary data or confidential information submitted by the applicant.

Product Development Protocols (PDPs)

The 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act allowed for two product pathways for a class III device: the PMA or, with prior FDA permission, the notice of completion of a PDP. The PDP process is based upon early consultation between the sponsor and the FDA leading to a device development and testing plan acceptable to both parties. It minimizes the risk that the sponsor will unknowingly pursue — with the associated waste of capital and other resources — the development of a device that FDA will not approve. The PDP plan incorporates four discrete stages of FDA review during the device design process: a PDP Summary Outline; FDA/Advisory Panel review of the full PDP; consideration and, where appropriate, pre-approval of design modifications and protocol revisions made during execution of the PDP; and action on the sponsors Notice of Completion. FDA review of the PDP summary may take up to 30 days; the review of the full PDP may take up to 120 days; and FDA must declare the PDP “completed” or “not completed” within ninety days of receiving the Notice. If the FDA finds that the Notice — together with other information previously submitted — shows that the requirements of the PDP, including Quality

System Regulation Inspection (or GMP inspection in the case of sponsors without an established satisfactory inspection history) has been met, the Agency will declare the PDP complete.

Humanitarian Device Exemptions (HDEs)

An HDE application is essentially the same as a PMA in both form and content but is exempt from the effectiveness requirement of a PMA. Even though the HDE is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose, the application must contain sufficient information for FDA to determine, as required by statute, that the device does not pose an unreasonable or significant risk of illness or injury to patients and that the probable benefit to health outweighs the risk of injury or illness from its use. An HDE application must also contain information that will allow FDA to make the other determinations required by the act. An approved HDE authorizes marketing of the humanitarian use device (HUD).

PMA Supplements

After a PMA is approved, the PMA holder may request FDA approval of changes to be made. For example, it may request changes to the device, its labeling or packaging, or the manufacturing processes used in its production. Unless prior approval is expressly not required by the PMA regulation, changes that affect the safety or effectiveness of the device require FDA premarket approval. FDA's review of a PMA supplement may be easy or difficult depending on the type of device, the significance of the change, and the complexity of the technology. Some PMA supplements can be as complex is the original application. Although the statutory timeframe is 180 days for PMA Supplements, FDA is committed to reviewing these in shorter timeframes and has reduced review timeframes through the use of real-time supplement process, 30-day notices, and expedited reviews.

Investigational Device Exemptions (IDEs)

Under the Act and Regulations, an individual, institution or company may sponsor the clinical investigation of a medical device to establish its safety and effectiveness. Before conducting a clinical trial, however, the sponsor must obtain the approval of an institutional review board (IRB) as well as informed consent from the study subjects at the time of their enrollment in the study. If the investigational device study presents a significant risk to the subjects, the sponsor must obtain FDA's approval of an "investigational device exemption" application (IDE) under 21 *CFR* 812. The IDE must contain information concerning the study's investigational plan, report of prior investigations, device manufacture, IRB actions, investigator agreements, subject

informed consent form, device labeling, cost of the device, and other matters related to the study. FDA has 30 calendar days from the date of receipt of the application to approve or disapprove an IDE submission.

IDE Amendments

Although not provided for in the IDE regulations, all submissions related to an original IDE that has been submitted, but not approved, are referred to as "IDE amendments". After an IDE is approved, related submissions are called "supplemental applications" under the regulations. Identification of IDE amendments enables FDA to track each IDE from the time it is originally submitted until the time it is approved.

IDE Supplements

The IDE regulation requires the sponsor of an investigation of a significant risk device to submit a supplemental application for a number of reasons. For example, a sponsor must submit a supplement if there is a change in the investigational plan when such a change may affect the scientific soundness of the study or the rights, safety, or welfare of the subjects. Supplemental applications also are required for the addition of investigational sites. This regulation also requires the submission of various reports, which are logged in as supplements to IDE applications. These include reports on unanticipated adverse effects of the device; recall and device disposition; failure to obtain informed consent; and annual progress reports, final reports, investigator lists, and other reports requested by FDA.

Premarket Notifications (510(k))

At least 90 days before placing a medical device into commercial distribution, a person required to register must submit to FDA a premarket notification, commonly known as a "510(k)." The exception to this is if the device is exempt from the 510(k) requirements of the Act by statute or regulation. In addition to other information concerning the device, e.g., a description of the device, a 510(k) summary or a 510(k) statement, the 510(k) submitter must include information to substantiate that the device is "substantially equivalent" to a legally marketed device that is not subject to premarket approval. A substantially equivalent device is marketed subject to the same regulatory controls as the device to which it is found to be substantially equivalent. A device may not be marketed pursuant to a 510(k) until the submitter receives written clearance from FDA.

Appendix B – ODE Publications

The following is a bibliography of articles and abstracts prepared by the ODE staff and published or presented during FY 2003.

Journals, Newsletter Articles and Book Chapters

Abel DB. Ongoing FDA Evaluation of Approved Endovascular Grafts. *J Vasc Surg*. 37(4):902-903, 2003.

Abel DB. FDA Advisory Panels. *Endovascular Today* 1(2):63-65, 2002.

Abel DB. Investigational Device Exemptions. *Endovascular Today* 2(1):51-52, 2003.

Abel DB. Off-label Medical Device Use. *Endovascular Today* 2(2):60-61, 2003.

Abel DB. Expanded Access. *Endovascular Today* 2(3):67-68, 2003.

Abel DB and Smith LJ. The ISO Standard for Endovascular Grafts. *Endovascular Today* 2(5):56-58, 2003.

Abel DB. Crime and Punishment. *Endovascular Today* 2(6):84-86, 2003.

Arepalli SR, Bezabehm S, and Brown SL. Allergic Reaction to Platinum in Silicone Breast Implants. *J Long-Term Effects of Medical Implants* 12(4):299-306, 2002.

Ashar BS and Schultz D. Surgical Technology: A Perspective from the FDA. *Bulletin of the American College of Surgeons* 88(3):32-33, 2003.

Baker KH. Of Special Interest: The Food and Drug Administration: A Partner in Safe Practice. *ORL Head and Neck Nursing* 21(2):25-27, Spring 2003.

Baker KH. Of Special Interest: A Review of Research Strategies for Clinicians. *ORL Head and Neck Nursing* 20(3):23-24, 2002.

Boam AB, Eydelman MB, Lum FC, Silverman PM, Apple DJ, Werner L, and Pandey SK. Retrospective Evaluation of Intraocular Lenses In Adults Younger Than 60 Years. *J Cataract Refract Surg*. 29(3):575-587, 2003.

Burnett TA, Mann EA, Cornell SA, and Ludlow CL. Laryngeal Elevation Achieved by Neuromuscular Stimulation at Rest. *J Appl Physiol* 94(1):128-134, 2003.

Chesler NC and Enyinna OC. Particle Deposition in Arteries Ex Vivo: Effects of Pressure, Flow, and Waveform. *J Biomechanical Engineering* 125:(3)389-394, 2003.

Ciarkowski AA. Empowering Patients: Total Product Life Cycle for Medical Devices. In Information Technology Business Models for Quality Health Care: An EU/US Dialogue. Edited by S. Krishna, E.A. Balas, and S.A. Boren, IOS Press, Amsterdam, 2003.

Drum B. Aberration Analyses Needed for FDA Evaluation of Safety and Effectiveness of Wavefront-Guided Refractive Surgical Devices. *J. Refract. Surg*. 19(5):S588-S591, September/October 2003.

Harvey ED and Whang JM. Preclinical Testing Guidelines for New Abdominopelvic Adhesion Barriers. *Infertility and Reproductive Medicine Clinics of North America* 14: 481-487, 2003.

Ho C and Kurtzman SB. Issues in Using Databases of Pre-recorded Physiological Signals to Test Medical Devices. *Biomedical Sciences Instrumentation* 39:169-174, 2003.

Holden JP, Selbie WS, and Stanhope SJ. A Proposed Test to Support the Clinical Movement Analysis Laboratory Accreditation Process. *Gait and Posture* 17(3):205-213, 2003.

Malshet V. Ear Candles: FDA's Regulatory Action and Current Position. *American Academy of Otolaryngology-Head and Neck Surgery Bulletin*, June 2003.

Ogden N. FDA Regulation of Technology and Surgical Devices in the Operating Room. *Seminars in Laparoscopic Surgery* 10(3):115-119, September 2003.

Payne C, Van Kerrebroeck P, Blaivas J, Herrera H, Chaikin D, Jonas U, Kusek L, Mattiasson A, Nyberg L, Peters T, Stothers M-A, and Webers A. Research Methodology in Urinary Incontinence. In Incontinence. Edited by P. Abrams, L. Cardozo, S. Khoury, and A. Wein. 2nd International Consultation on Incontinence. 2nd Edition 2002.

Pilcher G, Abel DB, and Homire SA. The FDA Medical Device Fellowship Program. *Endovascular Today* 2(4):59-61, 2003.

Preminger GM, Pearle MS, Stoller M L, Dore B, Herrera H, Herhej S, and Tolley DA. Quantification of Stone Patient. In Stone Disease. Edited by J. Segura, P. Conort, S. Khoury, C. Pak, G.M. Preminger, and D. Tolley. 1st International Consultation on Stone Disease. Edition 2003.

Puls I, Jonnakuty C, LaMonte BH, Holzbaur EL, Tokito M, Mann E, Floeter MK, Bidus K, Drayna D, Oh SJ, Brown RH, Ludlow C, and Fishbeck KH. Mutant Dynactin in Motor Neuron Disease. *Nature Genetics* 33(4):455-456, 2003.

Reefhuis J, Honein MA, Whitney CG, Chamany S, Mann EA, Biernath K, Broder K, Manning S, Avashia S, Victor M, Costa P, Devine O, Graham A, and Boyle C. Risk of Bacterial Mengitis in Children with Cochlear Implants. *New Engl J Med* 349(15):435-45, 2003.

Sacks W. Estimating the Effect of Computer-Aided Detection on Sensitivity of Screening Mammography. *Radiology* 226(2):597-598, February 2003.

Saviola J. Guest Perspective Editorial - Contact Lens Adverse Event Reporting. *Contact Lens Spectrum* 18(6):15, June 2003.

Saviola J. Soft Plano Contact Lenses: Medical Devices or Not? *Review of Optometry* 140(4): April 2003.

Saviola J. A Closer Look at FDA Contact Lens Labeling, *Contact Lens Spectrum* 18(1):44, January 2003.

Saviola J, Hilmantel G and Rosenthal AR. The U.S. Food and Drug Administration's Role in Contact Lens Development and Safety. *Eye and Contact Lens* 29(1):S160-S165, January 2003.

Toy J, Norton JS, Jibodh SR, and Adler R. Effects of Homeobox Genes on the Differentiation of Photoreceptor and Nonphotoreceptor Neurons. *Investigative Ophthalmology and Visual Sciences* 43(11):3522-9, November 2002.

Wagner RF, Beiden SV, Campbell G, Metz CE, and Sacks W. Assessment of Medical Imaging and Computer-assist Systems: Lessons from Recent Experience. *Academic Radiology* 9(11):1264-77, November 2002.

Abstracts and Presentations

Abel DB. Similarities and Differences Between the US and European Regulatory Processes. International Symposium on Endovascular Therapy, Miami, FL, January 20, 2003.

Abel DB. CARESS and Discussion of the FDA Versus CE Mark in the Regulatory Process: There is a Difference. Does it Matter? International Congress XVI Endovascular Interventions, Phoenix, AZ, February 11, 2002.

Abel DB. Biomaterials Educational Needs: A Regulatory Perspective. 2003 Society for Biomaterials Workshop entitled "Pathways to Successful Careers: Improving the Interface between Industry and Academia Through Education," Reno, NV, April 30, 2003.

Abel DB. Preclinical Testing: What Does the FDA Believe is Required? Endovascular 2003 and Beyond, Salt Lake City, UT, July 20, 2003.

Abel DB. Regulatory Issues for Graft and Stent Graft Design. Stent Technologies in Endoluminal Therapies Summit, Cleveland, OH, September 11, 2003.

Abel DB. Regulation of Endovascular Grafts: Lessons from the Last Few Years. Transcatheter Cardiovascular Therapeutics, Washington, DC, September 18, 2003.

Baker K. Alternative and Complementary Treatments the Symptoms of Sinusitis. Society of Otolaryngology and Head and Neck Nurses, San Diego, CA, September 2002.

Berman M. FDA Issues in the Evaluation of New Devices for Acute Heart Failure and Cardiogenic Shock. Transcather Cardiovascular Therapeutics, Washington, DC, September 18, 2003.

Boam A. Common Questions Asked of FDA. Town Hall Meeting with FDA CRT 2003, Washington, DC, January 28, 2003.

Boam A. Drug-Eluting Stents: Drug Substance - New vs. Approved. Town Hall Meeting with FDA at CRT 2003, Washington, DC, January 29, 2003.

Boam A. Evolving Regulatory Pathways for Coronary Drug-Eluting Stents. CRF Drug-Eluting Stent Symposium at the American College of Cardiology Annual Meeting, Chicago, IL, March 26, 2003.

Boam A. Drug-Eluting Stents - Current Approach to Review. FDA Workshop: Innovative Systems for Delivery of Drugs and Biologics, Bethesda, MD, July 8, 2003.

Boam A. Current and Evolving Regulatory Considerations for Biomarker Endpoints in AMI Device Trials. Transcatheter Cardiovascular Therapeutics, Washington, DC, September 2003.

Boam A. Drug-Eluting Stent Clinical Trials: Round 2. Transcatheter Cardiovascular Therapeutics, Washington, DC, September 18, 2003.

Boam A. Articulating the FDA Approval Pathway for a Drug-Eluting Stent System. Transcatheter Cardiovascular Therapeutics, Washington, DC, September 19, 2003.

Bowley SM and Malinauskas RA. Evaluation of Parameters Affecting Bovine Blood Hemolysis Testing. ASME Summer Bioengineering Conference, Key Biscayne, FL, June 25-29, 2003.

Carey CC. Innovations in AED Technology: The Need for Clinical Data. The 7th Wolf Creek Conference on Cardiopulmonary Resuscitation, Rancho Mirage, CA, June 13-16, 2003.

Cricenti P. Regulatory Issues of Needle Destruction Devices, Global Alliance for Vaccines and Immunization Research and Development Task Force New Technologies Group, Geneva, Switzerland, October 28-29, 2002.

Cricenti P. Regulatory Issues of Needle Destruction Devices, Global Alliance for Vaccines and Immunization Research and Development Task Force New Technologies Group, Geneva, Switzerland, February 10-13, 2003.

Doyle R and Stern S. Consideration of New Radiation Safety Standards for CT Equipment. A Diagnostic Imaging Conference on New Modalities and Radiation Safety (cosponsored by the Queen's University and the Hawaii Department of Health in partnership with the American College of Radiology). Honolulu, Hawaii, February 23, 2003

Drum B. Aberration Analyses Needed for FDA Evaluation of Safety and Effectiveness of Wavefront-Guided Refractive Surgical Devices. 4th International Congress of Wavefront Sensing and Aberration-Free Refractive Correction, San Francisco, CA. February 15, 2003.

Drum B, Hilmantel G, and Eydelman M. Evaluating the Safety and Effectiveness of "Aberration-Free" Refractive Surgery. Ninth FDA Science Forum, Washington, DC, April 24-25, 2003.

Drum B. FDA Regulation of Labeling and Promotional Claims in Marginally Effective Color Vision Devices. 17th Symposium of the International Color Vision Society, Seattle, WA, July 11-15, 2003.

Durfor CM. Challenges in Cell-based Therapeutics in Dermatology. Joint Meeting of Japanese Society for Investigative Dermatology, European Society for Dermatological Research Annual Meetings and Society for Investigative Dermatology, Miami, FL, May 1, 2003.

Foy JR. Common "Pitfalls" in Drug-Eluting Stent Applications. Cardiovascular Revascularization Therapy Conference, Washington, DC, January 29, 2003.

Foy JR. Drug-Device Combination Products: Device Perspective. 39th Annual Meeting of the Drug Information Association, San Antonio, TX, June 16, 2003.

Foy JR. Drug-Eluting Coronary Stents: A Case Study (Challenges & Outcomes). 39th Annual Meeting of the Drug Information Association, San Antonio, TX, June 17, 2003.

Foy JR. FDA's Top Ten List for Drug-Eluting Stents. Transcatheter Cardiovascular Therapeutics Conference, Washington, DC, September 18, 2003.

Gatling RR. Bundling Multiple Devices in a Single Application. AdvaMed's 13th Annual Device Submissions Workshop, Washington, DC, June 4, 2003.

Goode JL. Best Practices to Get an IDE Approved for a Peripheral Drug Eluting Stent. Cardiac Revascularization Therapy 2003, Washington DC, January 29, 2003.

Goode JL. Peripheral Drug Eluting Stents: Similarities To and Differences From Coronary Drug Eluting Stents. Transcatheter Cardiovascular Therapeutics, Washington, DC, September 18, 2003.

Harvey ED. Preclinical and Clinical Testing of Peripheral Drug-Eluting Stents. FDA Town Hall Meeting, Cardiovascular Revascularization Therapies Annual Meeting, January 2003.

Harvey ED. Regulatory Considerations for Carotid Stent Trials. International Society of Endovascular Specialists 10th Annual Meeting, Phoenix, AZ, February 2003.

Harvey ED. Regulatory Considerations for Biliary versus vascular stents. Stent Summit, Cleveland Clinic, Cleveland, OH, September 11, 2003.

Harvey ED. Carotid Stenting: an FDA Overview. Transcatheter Cardiovascular Therapeutics, Washington, DC, September 18, 2003.

Harvey ED. Peripheral Stenting: an FDA Overview. Transcatheter Cardiovascular Therapeutics, Washington, DC, September 18, 2003.

Hawthorne CA. Using Regulations, Standards, and Guidance Documents to Strengthen Your Regulatory Strategy. Regulatory Affairs Professional Society (RAPS) Annual Conference, Washington, DC, October 2002.

Hilmantel G. FDA Post-Approval Clinical Studies of 30-Day Extended Wear Contact Lenses, American Academy of Optometry, San Diego, CA, December 2002.

Ho C and Kurtzman SB. Issues in Using Databases of Pre-Recorded Physiological Signals to Test Medical Devices, Rocky Mountain Bioengineering Symposium, Biloxi, MS, April 2003.

Hudson PL. CDRH Regulation of Tissue Engineered Products. 7th Annual Engineering Tissues Workshop, Hilton Head, SC, February 26 – March 1, 2003.

Kaiser AD. Science-based Testing for Combination Devices. The National Academies' Biomedical Engineering Materials and Applications (BEMA) Roundtable–"Science-based Assessment: Accelerating Product Development of Combination Medical Devices," Washington, DC, April 22-23, 2003

Kammula R. Use of International Standards in the Biocompatibility Evaluation of Medical Devices. American College of Toxicologists (annual meeting), Hershey, PA, October 10, 2002.

Kammula R. Convened and chaired the Working Group 9 (Effects on Blood) committee meeting at ISO TC 194, "Biological Evolution of Medical Devices," Alexandria, VA, April 7-11, 2003.

Mallis E. FDA Perspective on Novel Diagnostic Catheters. American College of Cardiology, Chicago, IL, March 29, 2003.

Malshet V. FDA Regulation of Cochlear Implants. Cochlear Implants Symposium at the First International Conference on Medical Implants, Bethesda, MD, July 27, 2003.

Mann E. Meningitis in Cochlear Implant Recipients. 2003 International Pediatric Cochlear Implant Meeting, Washington, DC, April 24, 2003.

Melkerson M. OSMA Orthopedic and Restorative Update. Alexandria, VA, October 25, 2002.

Melkerson M and Stevens T. OSMA Orthopedic and Restorative Update. Annapolis, MD, April 25, 2003.

Mitchell D. Clinical Investigator Responsibilities for Medical Device Investigations. Annual Clinical Investigator Conference sponsored by the Univ. of Washington, Seattle, WA, May 2003.

Morris J. CDRH's Current Regulatory Approach for Antimicrobial Coated Medical Devices as well as Combination Products, at the Center for Biofilm Engineering Technical Advisory Conference (TAC), Bozeman, MO, July 22-24, 2003.

Nguyen T. Modular and Expedited PMA Updates. Medical Device Alley, Minneapolis, MN, June 2003.

Nutter C. Participated in a Medical Packaging Roundtable teleconference discussion in London, England. October 2002. Highlights of the teleconference were published as an article entitled "Medical Packaging Roundtable: Standardizing a Global Approach to Packaging" (Harmonizing ISO 11607 and EN 868-1) in Pharmaceutical & Medical Packaging News, December 2002.

Nutter C. Requirements for Products Labeled 'STERILE' (focusing on SAL for terminally sterilized and contamination rate for aseptically processed products and addressing two standards: EN 556 and AAMI ST67). 13th Annual AAMI/FDA International Conference on Medical Device Standards and Regulation, Washington, DC, March 11-12, 2003.

Pinto H. Regulatory Considerations for Various CPR Devices, Palm Springs, CA, June 2003.

Pluhowski NJ. MDUFMA Pediatric Provisions and Advisory Panel Update. The 6th Annual FDA-OCRA Educational Conference--FDA & OCRA: Understanding The Changing Landscape, Irvine, CA, June 2003.

Pluhowski NJ. PMA Filing. The 6th Annual FDA-OCRA Educational Conference--FDA & OCRA: Understanding The Changing Landscape, Irvine, CA, June 2003.

Pollard C. Regulatory Considerations for Medical Device Development. Harvard-MIT Biomedical Enterprises Program, Boston, MA, April 2003.

Provost M. Regulatory Approaches for Biological/Device Combination Products. CDRH Drug Information Association Annual Meeting, San Antonio, TX, June 2003.

Provost M. CDRH Perspective on Regulation of Tissue Engineered Medical Products. Engineering Tissue Growth International Conference and Exposition, March 2003.

Rhodes SP. CDRH Perspective on the Regulation of Novel Wound Dressings. DARPA Wound Healing Workshop, Annapolis, MD, September 23, 2003.

Rhodes SP. Clinical Studies and Least Burdensome Issues. MassMedic, Boston, MA, March 28, 2003.

Romanell LJ. 510(k) MDUFMA Update. AdvaMed's 13th Annual Device Submissions Workshop, Washington, DC, June 4-5, 2003.

Rosecrans HS. Understanding When to Submit a 510(k) and the General vs. Specific Labeling Guidance. AdvaMed/MTLI Seminar, Alexandria, VA, February 2003.

Rosecrans HS. 510(k) Program Update. Regulatory Affairs Professional Society 2003 Medical Device Conference, San Francisco, CA, March 2003.

Rosecrans HS. 510(k) Program Update. 6th Annual FDA-Orange County Regulatory Affairs Education Conference, Irvine, CA, June 2003.

Rosenthal AR and Eydelman M. Regulation of Medical Devices. Annual Meeting of American Academy of Ophthalmology, Orlando, FL, October 2003.

Rosenthal AR. Promote FDA to Corporate Ophthalmology. American Academy of Ophthalmology – Corporate Advisory Council, San Francisco, CA, September 2003.

Saviola J. Color Additives in Medical Devices. FDA, Center for Food Safety and Applied Nutrition (CFSAN) Office of Food Additive Safety, Regulatory Grand Rounds, March 11, 2003.

Saviola J. Regulation of Contact Lenses. Association of Regulatory Boards of Optometry (ARBO) Annual Meeting, Contemporary Issues Symposium, San Diego, CA, June 2003.

Schultz D. FDA Regulation of Medical Devices: Today and Tomorrow. University of Colorado, Denver, CO, February 2003.

Schultz D. FDA Regulation of Medical Devices: Today and Tomorrow. St. Joseph Hospital, Denver, CO, February 2003.

Schultz D. FDA Regulation of Medical Devices: Today and Tomorrow. Laparoscopy Meeting, Vail, CO, February 2003.

Schultz D. General/Specific Revisited. AdvaMed, Washington, DC, February 2003.

Schultz D. The Medical Device Product Lifecycle; Is the Concept Worth Developing? DIA, San Francisco, CA, February 2003.

Schultz D. Workshop: Key Issues in Trial Design for Devices in Heart Failure. Heart Failure Society of America, Washington, DC, February 2003.

Schultz D. FDA Initiatives. Regulatory Affairs Professional Society (RAPS), San Francisco, CA, March 2003.

Schultz D. FDA Update. North American Society for Pacing and Electrophysiology (NASPE), Tysons Corner, VA, April 2003.

Schultz D. CDRH Update. Orange County Regulatory Affairs (OCRA), Irvine, CA, June 2003.

Schultz D. Safe and Effective/Reasonable and Necessary: A CDRH Perspective. Heart Failure Society of America, September 2003.

Schultz D. FDA's Perspective on Risk in Medical Devices. Regulatory Affairs Professional Society (RAPS), Baltimore, MD, October 2003.

Schultz D. The Changing World of Medical Devices. Wisconsin Biotechnology Association, Madison, WI, November 2003.

Shulman M. Introduction to 510(k) Submissions. Advanced Issues in Premarket Notification. Medical Design and Manufacturing (MD&M) West Conference, Anaheim, CA, February 2003.

Shulman M. Premarket Notification. AMDM In Vitro Diagnostics 510(k) Workshop, Rockville, MD, April 2003.

Shulman M. Introduction to 510(k) Submissions. Advanced Issued in Premarket Notification. Medical Design and Manufacturing (MD&M) East Conference, New York City, NY, June 2003.

Swain J. "Women and Cardiovascular Device Trials". USC Symposium on Women and Cardiovascular Disease, Laguna Niguel, CA, June 2003.

Swain J. The FDA and Devices for Heart Failure. American Heart Association, San Diego Chapter, CA, April 4, 2003.

Swain J. Clinical Perspectives on Patient Selection and Endpoints for Heart Failure Trials. Transcatheter Cardiovascular Therapeutics, Washington, DC, September 18, 2003.

Swain J. Clinical Trials for AMI Devices: Design, Endpoints, and Surrogate Markers. Transcatheter Cardiovascular Therapeutics, Washington, DC, September 18, 2003.

Swain J. Septal Defect and Left Atrial Appendage Closure Devices: Recent Experiences and Perspectives on Pathways for Regulatory Approval. Transcatheter Therapeutics meeting, Washington, DC, September 18, 2003.

Swain J. Percutaneous Valve Replacement and Implantable Devices for Valve Repair. Transcatheter Therapeutics meeting, Washington, DC, September 18, 2003.

Tillman DB. Modifications to PMA-approved devices: a view from the trenches, RAPS Annual Meeting, Washington, DC, October 2002.

Tillman DB. Overview of Issues Involving Pacing Device Approval for CHF Indications. Heart Failure Society of American Workshop – Trial Design for Heart Failure Devices, Rockville, MD, February 27, 2003

Tillman DB. The More the Merrier: DCD's experience with the Medical Device Fellowship Program. ASAIO Regulatory Workshop, Washington, DC, June 2003.

Tillman DB. Cardiovascular Device Update. AdvaMed Medical Device Submission Workshop, Rockville, MD, June 2003.

Warburton K. FDA Update. American National Standards Institute (ANSI) Committee Z80 for Ophthalmic Device Standards, Ft. Lauderdale, FL, March 2003.

Weitershausen J. FDA Clearance and Medical Device Issues – Oxygen Equipment. Oxygen Standardization Coordinating Group Annual Meeting, Davenport, IA, June 2003.

Whipple D. FDA Update. American National Standards Institute (ANSI) Committee Z80 for Ophthalmic Device Standards, Baltimore, MD, October 2002.

Witten CM. Regulation of Neurological Devices. A Conversation with Neurological Disease Patient Advocacy Organizations, Rockville, MD, April 24, 2003.

Witten CM. Plastic and Reconstructive Surgery Device Issues. FDA International Visitors from Ireland, Rockville, MD, May 14, 2003.

Witten CM. RHAIR. Society for Academic Emergency Medicine, Boston, MA, May 31, 2003.

Witten CM. DBS Viewed from FDA. DBS Consortium Meeting, Washington, DC, September 30, 2003.

Witten CM. Standards: Implementations by CDRH. ASTM Tissue Engineering Symposium, Miami, FL, November 5, 2002.

Wolanski N. PMA Update: Assessing User Fees and PMA Filing. Medical Device Alley, Minneapolis, MN, June 2003.

Zimmerman BA. FDA Regulation of Orthopedic Devices. Medical Implant Conference, Bethesda, MD, July 28, 2003.

Appendix C – OIVD Publications

Journals, Newsletter Articles and Book Chapters

Gutman S, Bernhardt P, Pinkos A, Moxey-Mims M, Knott T, and Cooper J. Regulatory Aspects of Invasive Glucose Measurements. *Diabetes Technology & Therapeutics* 4(6):775-777, 2002.

Gutman S, Bernhardt P, Pinkos A, Moxey-Mims M, Knott T, and Cooper J. Regulatory Aspects of Non-Invasive Glucose Measurements. *Diabetes Technology & Therapeutics* 4(6):779-781, 2002.

Lesko LJ, Salerno RA, Spear BB, Anderson DC, Anderson T, Brazell C, Collins J, Dorner A, Essayan D, Gomez-Mancilla B, Hackett J, Huang S-M, Ide S, Killinger J, Leighton J, Mansfield E**,** Meyer R, Ryan SG, Schmith V, Shaw P, Sistare F, Watson M, and Worobec A. Pharmacogenetics and Pharmacogenomics in Drug Development and Regulatory Decision-Making: Report of the First FDA-PWG-PhRMA-DruSafe Workshop. *J. Clin. Pharmacol.* 43:342-358, 2003.

Mansfield E. Genetic Testing and Personalized Medicine: An FDA View. *Preclinica* 1(4):155-158, 2003.

Schoonmaker M, Bagley G, and Scanlan M. Coordination of Federal Regulation and Payment for New Diagnostic Tests: A Proposed New Approach. *Food and Drug Law Journal* 57(2):195-204, 2002.

Schoonmaker M. The Third Party Payer System and Coverage Decision-Making and (Chapt 7) Payment Policy, Billing Practice and Specialty Issues. In Manual on Reimbursement for Medical Genetics Services. Edited by M.S. Williams. American College of Medical Genetics, Rockville, MD, 2002.

Abstracts and Presentations

Altaie S, Bautista J, Benson C, Callaghan J, Chesler R, Cooper J, Poole F, Shively R, and St. Pierre D**.** All You Want to Know About 510(k) Submissions for IVDs. Association of Medical Diagnostics Manufacturers 510(k) Workshop, Rockville, MD, April 22, 2003.

Bernhardt P. FDA Oversight of New Glucose Diagnostic Devices. The Second La Jolla Conference on Glucose Monitoring and Control, La Jolla, CA, February 13 -17, 2003.

Callaghan J. Software Requirements for Part 11 and an Overview of Software Guidance Documents. The Regulatory Affairs Professionals Society meeting, San Francisco, CA, November 4-5, 2002.

Chan M. The Impact of Standards on Determining the Approvability of Multiplexed RNA-based In Vitro Diagnostic Tests. NIST sponsored workshop on "Metrology and Standards Needs for Gene Expression Technologies: Universal RNA Standards", Palo Alto, CA, March 27-30, 2003.

Chan M. Genomics-based Diagnostics - FDA Perspectives. MD Anderson Cancer Center sponsored Cancer Therapeutics Discovery Program Workshop on "Designing integrated clinical trials for "response-marker" discovery with novel biologically targeted agents", Houston, TX, April 25-26, 2003.

Chan M. The Role of FDA in the Regulation of in vitro Diagnostics. The Fourth Principal Investigator's Meeting of the Innovative Molecular Analysis Technologies Program, San Diego, CA, June 6-18, 2003.

Ellis C. Women and Cardiovascular Disease. FDA Women's Equality Day Educational Seminar, Jamaica, NY, August 4, 2003.

Magruder L. Determine Daily Workload Limits for Cytotechnologists Using New Technologies that Locate and Mark the Location of Abnormal Cells on a Pap Slide. Cytopathology Education and Technology Consortium (CETC), Salt Lake City, UT, November 7, 2002.

Mansfield E and Schoonmaker M. Points to Consider in Microarray Test Development. Association of Medical Device Manufacturers, Rockville, MD, April 24, 2003.

Poole F. Malaria Microscopy – Issues in Clinical Trials. American Society for Tropical Medicine & Hygiene Conference, Denver, CO, November 11-13, 2002.

Poole F. FDA Perspectives on Using Commercial NAAT Kits. Association of Public Health Laboratories Conference, Denver, CO, March 5-7, 2003.

Robinowitz M. FDA Regulation of Tumor Marker In Vitro Diagnostic Tests. C-Kit Standardization Expert Panel. College of American Pathologists Meeting, Washington, DC, February 5, 2003.

Sauberman H, Cooper J, Bernhardt P, and Pinkos A. Regulatory Considerations for Invasive and Non-Invasive Glucose Measurement Devices. Abstract, 9th Annual FDA Science Forum, Rockville, MD, 2003.

Sheldon A, Altaie S, Marsik F, Silver H, and Unowsky J. Guidance for Industry Document-Development, Analysis, and Presentation of Microbiological Data for Antibacterial Drug Products. Abstract X-05, p.199, 9th Annual FDA Science Forum, Rockville, MD, 2003.

Shively R. Poxvirus and Other Febrile Vesicular Rash Illness Diagnostic Testing. The National Center for Infectious Diseases (NCID) of the Centers for Disease Control and Prevention (CDC), in collaboration with the Association of Public Health Laboratories, and the American Society for Microbiology Symposium, San Diego, CA, October 1, 2002.

Shively R. Molecular Methods: Impact on Public Health Practice. Association of Public Health Laboratories Conference, Denver, CO, March 5-7, 2003.

Shively R. Overcoming Regulatory Hurdles. American Society of Microbiology Conference, Baltimore, MD, March 9, 2003.

Wright DK. How Decision Making Drives Viral Testing. Clinical Virology Symposium Annual Meeting of the Pan America Society for Clinical Virology, Clearwater, FL, April 27-30, 2003.

Staff College Presenters and Faculty

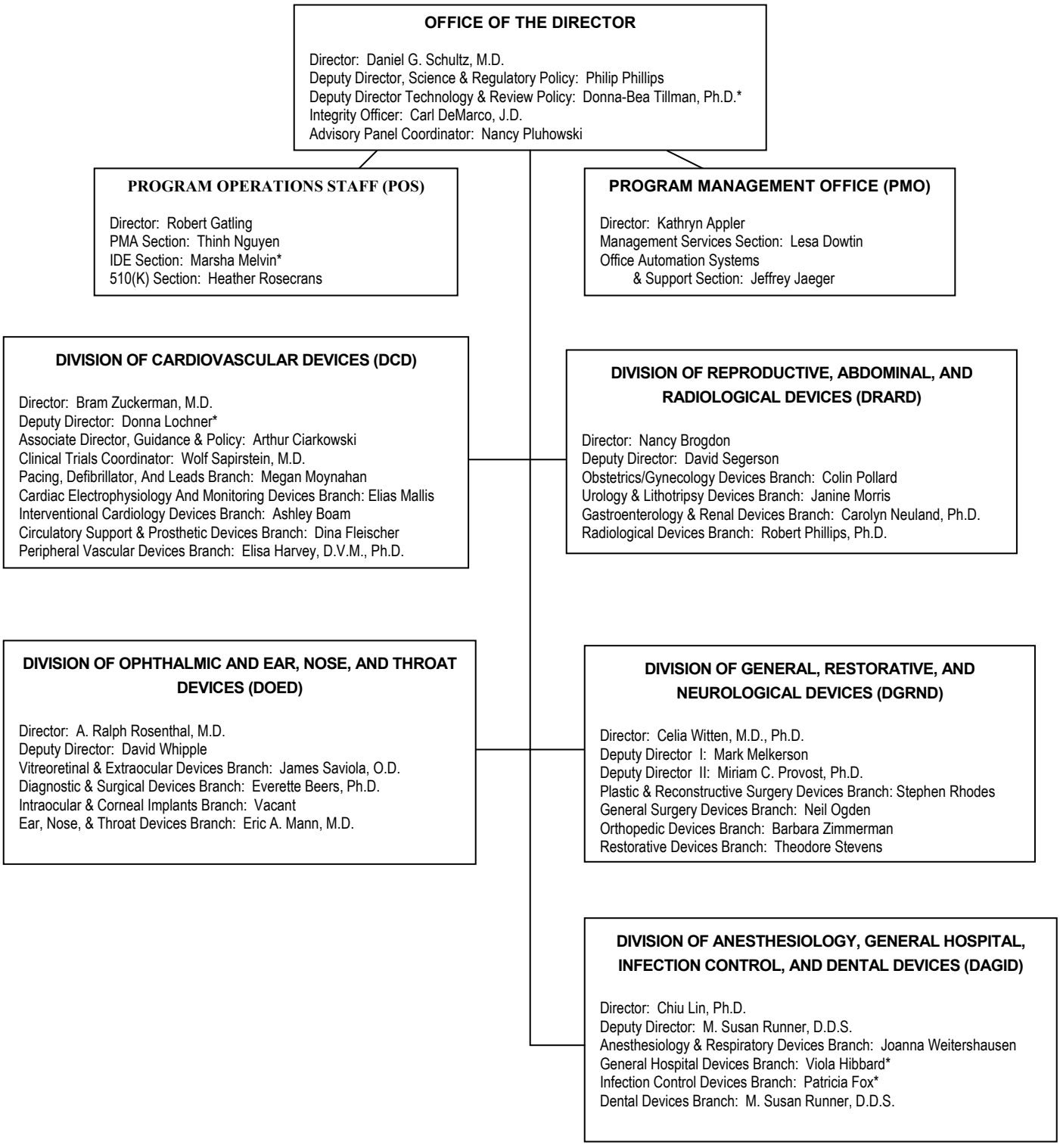
Baker, Karen
Berman, Michael
Chandeysson, Paul
Dawisha, Sahar
Eydelman, Malvina
Gutman, Steve
Harvey, Elisa
Hayden, Brenda
Hyde, John
Jensen, D. Nick
Kammula, Raja
Kane, James
Less, Joanne
Mann, Eric
Nguyen, Thinh
Nutter, Cathy
Pena, Carlos
Phillips, Philip
Phillips, Robert
Proestel, Scott
Provost, Miriam
Robinowitz, Max
Rosecrans, Heather
Sacks, William
Shulman, Marjorie
St. Pierre, Don
Tovar-Calderon, Oscar
Witten, Celia
Yustein, Ron
Zuckerman, Bram

Appendix D – Selected FDA Websites

Breast Implants: Consumer Information	http://www.fda.gov/cdrh/breastimplants/index.html
CDRH's Home Page	http://www.fda.gov/cdrh/index.html
Division of Small Manufacturers, International and Consumer Assistance	http://www.fda.gov/cdrh/consumer/index.html
Federal Advisory Committee Act Database	http://www.facadatabase.gov/public.asp
FDA's Home Page	http://www.fda.gov
Guidance Documents	http://www.fda.gov/cdrh/guidance.html
Instructions for Submitting Electronic Submissions	http://www.fda.gov/cdrh/elecsub.html
LASIK Eye Surgery: Learning About LASIK	http://www.fda.gov/cdrh/lasik/
Least Burdensome Provisions - Activities Related to Implementation	http://www.fda.gov/cdrh/modact/leastburdensome.html
MDUFMA Home Page	www.fda.gov/cdrh/mdufma
OIVD Home Page	http://www.fda.gov/cdrh/oivd
Panel Meeting Schedules and Summaries	http://www.fda.gov/cdrh/panel/index.html
Previously Approved/Cleared Device Databases	http://www.fda.gov/cdrh/consumer/mda/index.html#databases
Recent Device Approvals	http://www.fda.gov/cdrh/consumer/mda/index.html
Recruitment Brochure for Members and Consultants to the Medical Devices Advisory Committee	http://www.fda.gov/cdrh/ode/advbrochure01.html
Standards of Ethical Conduct	http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/reference/rfsoc_99.pdf
Third Party Review	http://www.fda.gov/cdrh/thirdparty

Appendix E – ODE Organization Chart

As of 01/26/04



*Acting

Appendix F – OIVD Organization Chart

As of 01-22-04

OFFICE OF THE DIRECTOR

Director: Steve Gutman, M.D.
Deputy Director, New Device Evaluation: Donald St. Pierre
Deputy Director, Patient Safety and Product Quality: James Woods
Associate Director: Joseph Hackett, Ph.D.
Scientific Policy Advisor: Sousan S. Altaie, Ph.D.
Administrative Officer: David Warren

DIVISION OF MICROBIOLOGY DEVICES (DMD)

Director: Sally Hojvat, Ph.D.
Deputy Director: Freddie Poole

DIVISION OF IMMUNOLOGY AND HEMATOLOGY DEVICES (DIHD)

Director: Joseph Hackett, Ph.D. (Acting)

Immunology Team Leader: Maria Chan, Ph.D.
Hematology Team Leader: Josephine Bautista
Project Manager: James P. Reeves, Ph.D.

DIVISION OF CHEMISTRY AND TOXICOLOGY DEVICES (DCTD)

Director: Jean Cooper, D.V.M.

Toxicology Team Leader: Alberto Gutierrez, Ph.D.
Chemistry Team Leader: Carol Benson

Appendix G - ODE Staff Roster

Office of the Director

DeMarco, Carl
Gornick, MaryAnn
Hobbs, Cathy
Phillips, Philip
Pluhowski, Nancy
Schultz, Dan
Williams, Nailah

Program Management Office

Appler, Kathryn
Armani, Armin*
Colleli, Karen
Clingerman, Angie
Dowtin, Lesa
Dumas, Evalee
Harris, Nicholas*
Jaeger, Jeff
Koviack, Bob
Phillips, Shirley
Robins, Lisa
Schielke, Mary
Soto, Isella
Wedlock, Chuck

Program Operations Staff

Berk, Gene
Fisher, Lisa
Garcia, Diane
Gatling, Robert
Hawthorne, C. Ann
Less, Joanne
Lyons-Drager, Linda
Melvin, Marsha
Nguyen, Thinh
Parker, Mervin
Rechen, Eric
Romanell, Lawrence
Rosecrans, Heather
Sawyer-Major, Wanda
Simenauer, Paula
Shulman, Marjorie
Williams, Paul
Wolanski, Nicole

Division of Cardiovascular Devices

Abel, Dorothy
Anderson, Nelson
Barold, Helen
Berman, Michael
Boam, Ashley
Bowley, Susan
Brown, Michele
Buckles, David
Buckley, Donna
Carey, Carole
Cavanaugh, Kenneth
Chandeysson, Paul
Chen, Eric
Cheng, Jim
Ciarkowski, Art
Danielson, Judy
Demian, Cindy
Diallo, Mame*
Donelson, Jan
Enyinna, Kachi
Ewing, Lesley**
Faris, Owen
Fleischer, Dina
Foy, Joni
Foy, Keith
Gantt, Doyle
Goode, Jennifer
Harvey, Elisa
Heaton, Tom
Higginson, Kathy
Hill, Genevieve
Hillebrenner, Matthew
Ho, Charles
Holden, John
Holt, Vivianne

Hottenstein, Omar
Huynh, Ann
Hwang, Shang
Hyde, John
Jensen, Nick
Jones, Edwena
Kaiser, Suzanne
Kennell, Lisa
Kurtzman, Steve
Lacy, Frank
Lee, James
Lemperle, Bette
Letzing, Bill
Mallis, Elias
Mattera, Michelle
Mezu-Nwaba, Nina
Moynahan, Megan
Muni, Neal
Nell, Diane#
Peters, Kimberly
Pina, Illena*
Proestel, Scott
Ramdat, Deb
Reilly, Sabina
Richards, Robert
Ryan, Tara
Samadnejad, Sami
Sapirstein, Wolf
Shein, Mitchell
Smallwood, Senora
Smith, Angela
Stuhlmuller, John
Swain, Julie**
Swink, James
Terry, Doris
Tillman, Donna-Bea
Tovar-Calderon, Oscar
Ulmer, Kwame
Usher, Wil
Vaughan, Carolyn
Weintraub, Ron*
Wentz, Catherine
Wood, Geretta
Yuan, Jay
Zuckerman, Bram

Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices

Adjodha, Michael
Barrett, Sue
Bazaral, Mike
Betz, Robert
Bezabeh, Shewit
Blackwell, Angela
Blount, Sharon
Bolden, Brenda
Browne, Myra
Burdick, William
Chisley, India
Cricenti, Pat
Cunningham, Terrell
Dorsey, Regina
Floyd, Chirelle
Fox, Pat
Gantt, Gail
Guay, Justin
Harkavy, Lorraine
Harris, Lisa
Hibbard, Viola
Jordan, Erika
Lappalainen, Sharon#
Lin, Chiu
Marshall, Felicidad
Mayhall, Elaine
Mulry, Kevin
Nakayama, Von
Naveau, Irene
Noe, Bill
O'Connell, Linh
O'Lone, Martha
Patel, Neel
Pinto, Hina
Reid, Joy
Riley, Erin
Robinson, Mary Jo
Roy, Joydeb
Runner, Susan
Ryan, Michael
Sauberman, Harry
Schmidt, Jennifer
Scott, Pam

Smith, Gwendolyn
Soprey, Pandu
Teresinski, Doris
Tritschler, Elizabeth
Turtil, Steve
Ulatowski, Tim
Weitershausen, Joanna

Division of General, Restorative, and Neurological Devices

Allen, Peter
Allen, Samie
Anderson, Jodi
Arepalli, Sam
Ashar, Binita
Basu, Sankar
Berkowitz, David
Bernato, Dolores
Berne, Bernard
Bourke, Tracey
Bowsher, Kristen
Brown, Sheila
Buch, Barbara
Corn, David
Costello, Ann
Courtney, Mike
Dawisha, Sahar
De Del Castillo, Sergio
DeLuca, Bob
Demian, Hany
Durfor, Charles
Einberg, Elmar
Eudy, Mike
Felten, Richard
Ferriter, Ann**
Fogarty, Pauline
Frank, Elizabeth
Gantenberg, Julie
Goode, John
Hack, Chris
Hackey, Elise
Hammond, Della
Hardin, Calley
Hill, Ayanna
Hinckley, Steve
Horbowyj, Roxi
Hudson, Peter
Kaiser, Aric
Krause, David
Lee, Kevin
Lerner, Herb
Mattamal, George
Mattera, Michelle
Melkerson, Mark
Mishra, Nirmal
Ogden, Neil
Pak, Yung
Peck, Jonathan
Pena, Carlos
Phillips, Mary Ellen
Provost, Miriam
Rhodes, Holly
Rhodes, Stephen
Rossi, Jeff
Schlosser, Michael
Schroeder, Marie
Scudiero, Jan
Sloan, Nadine
Stevens, Ted
Stiegman, Glenn
Sturniolo, Mike
Sung, Pei
Tillman, Ahlia**
Vegas-Sala, Dora
Walker, Jeff
Warfield, Diane
Watson, Tony
Weiblinger, Rick
Witten, Celia
Wolf, Beverly
Wood, Gregory
Yahiro, Martin
Yen, Dwight
Zimmerman, Barbara

Division of Ophthalmic and Ear, Nose, and Throat Devices

Alexander, Kesia
Austin-Hansberry, Lori
Baker, Karen

APPENDIX G

Beers, Everette
Berman, Sheryl
Blustein, Joseph+
Brown, Daniel
Burke-Nicholas, Marsha
Buttemere, Clay
Callaway, Jan
Calogero, Don
Chen, Tzeng
Cohen, Ethan#
Cohen, Linda
Cunningham, Bradley
Cygnarowicz, Teresa
Drum, Bruce
Eydelman, Malvina
Falls, Deborah
Glover, Joel
Gouge, Susan
Hilmantel, Gene
Hoang, Quynh
Jaffe, Sidney
Jones, Susanna
Kane, James
Kaufman, Daryl
Lepri, Bernard
Leslie, Sharmeka
Lochner, Donna
Malshet, Vasant
Mann, Eric
McCarthy, Denis
McGhee, Eleanor
Moore, Shirley
Nandkumar, Srinivas**
Ortega, Maritze
Pereira, Antonio
Rorer, Eva
Rosenthal, Ralph
Saviola, James
Selfon, Eric
Shi, Dexiu
Shih, Ming-Chuen
Smith, Myra
Storer, Patricia
Thornton, Sara
Toy, Jeffrey
Warburton, Karen
Whipple, David

Division of Reproductive, Abdominal, and Radiological Devices

Bailey, Michael
Baxley, John
Bradley Allen, Cheryl
Brogdon, Nancy
Byrd, Laura
Byrne, Michelle
Carr, Linda
Chakrabarti, Kish
Chan, Dulciana
Chen, John
Cooper, Jeff
Cornelius, Mary Jo
Corrado, Julia
Czerska, Ewa
Dart, Linda
Daws-Kopp, Kathryn
Del Mundo, Noel
Doyle, Bob
Eba, Felisa
Gonzalez, Gema
Grillo, Greg
Herrera, Hector
Howell, Kimberly
Lauritsen, Kristina
Jevtich, Milorad
Kammula, Raju
Kang, Simkeon
Kuchinski, Mike
Lawrence, Lisa
Lutwak, Leo
Mackey, Cheryl
McCool, Barbara
Miller, Pat
Mitchell, Diane
Monahan, Jack
Morris, Janine
Neuland, Carolyn
Nimmagadda, Rao
Nipper, Joshua
Nutter, Cathy
O'Brien, Mary Beth
Oliver, Karen
Olvey, Kathleen
Perez, Rod

Phillips, Bob
Pollard, Colin
Price, Veronica
Rubendall, Rita
Sacks, William
Sauls, Mattie
Segerson, Dave
Seiler, Jim
Shoback, Barbara
Shuping, Ralph
Straughn, Kellie
Virmani, Mridu
Wersto, Nancy
Whang, Joyce
Williams, Dick
Zaremba, Loren
Zaudtke, Peter
Yustein, Ron

* Contractor
** ORISE Contractor
# Joint Appointment w/OST
+ MDUFMA Joint Hire w/OSB

Appendix H - OIVD Staff Roster

Office of the Director

Altaie, Sousan
Aziz, Kaiser
Ellis, Claudette
Fish, Robert
Garvin, Terri
Gonzalez-Licea, Agustus
Gutman, Steve
Hackett, Joe
Hanna, Nancy
Hoard, Renita
Latish, Andrea
Sliva, Clara
St. Pierre, Don
Staples, Broden
Vashio, Valerie
Warren, Duffy
Wei, Tena
Wilbon, Tonya
Woods, James

Division of Chemistry and Toxicology Devices

Benson, Carol
Bernhardt, Pat
Callaghan, Jim
Calvin, Veronica
Chesler, Ruth
Cooper, Jean
Danishefsky, Avis
Gutierrez, Alberto
Hall, Christina
Harper, Courtney
Hausman, Ethan
Ingram, Jr., Kenneth
Kellerman, Christine
Pinkos, Arleen
Rheinheimer, Doug
Sanhai, Wendy
Stafford, Elizabeth
Tsai, Miin-Rong
Wood, Doug

Division of Immunology and Hematology Devices

Bautista, Josephine
Blagmon, Djuana
Brindza, Larry
Carlos, Rufina
Chace, Nina
Chan, Maria
Dada, Valerie
Faison, Tremel
Jones, Cecily
Magruder, Louise
Mansfield, Elizabeth
McClain-Bennett, Joan
Michaud, Ginette
Moore, Deborah
O'Leary, Tim
Radha, Edappallath
Reeves, Pat
Robinowitz, Max
Schoonmaker, Michele
Stewart, Paula
Torres-Cabassa, Angel
Weeks, Susan

Division of Microbiology Devices

Beverly, Patricia
Brill, Marieann
Brock, Nadine
Del Mundo, Noel
Dubois, Woody
Gaffey, Claudia
Goldman, Tara
Heyliger, Marian
Hojvat, Sally
Poole, Freddie
Rao, Prasad
Rogers, Elizabeth
Selepak, Sally
Shaikh, Farzana
Shively, Roxanne
Simms, Tom

APPENDIX H

Summers, Peter
Whitaker, Kathleen
Wright, Kathy