OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 2000

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:

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ODE Review Divisions
ODE Program Management Office
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PREFACE

Dear Reader:

Welcome to our FY 2000 Annual Report. In many ways it's similar in form to last year's report. For example, it contains the expected listing of all approvals and clearances, the volume of submissions for the year and our relative productivity (turnaround time). Yet it differs from previous annual reports in that we've tried to make it more inviting and user-interesting.

For starters, we've highlighted our main accomplishments for the year. Second, we've illustrated our impact on patient care by presenting seven representative approvals and demonstrating their clinical usefulness. The patient, the health care worker and the commercial vendor can all identify with the clinical value of these "cutting edge" technologies. Lastly, on the style side, we've improved clarity and readability with a new format that uses a bit more color and some innovative design.

As in previous years, ODE continues to process a large number of submissions. Although the absolute number has not increased significantly over the past few years, the new technologies represented in these submissions are growing in complexity and in sophistication. Nonetheless, we continue to meet our statutory deadlines with few exceptions, and we'll strive to do even better in FY 2001.

We anticipate that not everyone will always agree with our decisions regarding the safety and effectiveness of new devices. That's inevitable, because those decisions, which must carefully combine science and the law, are often difficult to make. Despite the occasional disagreements, one thing remains clear: ODE as an organization, is committed to respond to all of our stakeholders—patients, clinicians and the industry in a fair, consistent, rational and compassionate manner.

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PREFACE

As I look back on my first year as ODE director, I feel a deep sense of responsibility, because I know that the decisions this Office makes under my leadership will have a profound effect on people's health and well being for years to come. I also feel great appreciation for the outstanding staff here in ODE.

Beyond their competence, in which I take great pride, I find the staff in ODE to be deeply committed to their task of protecting the public health and promoting new technology. They are the true authors of this report.

All the ODE managers and I hope you find this report useful, and that you enjoy reading it. Please send any comments to us at odereport@cdrh.fda.gov so that we can improve our annual reports in the years ahead.

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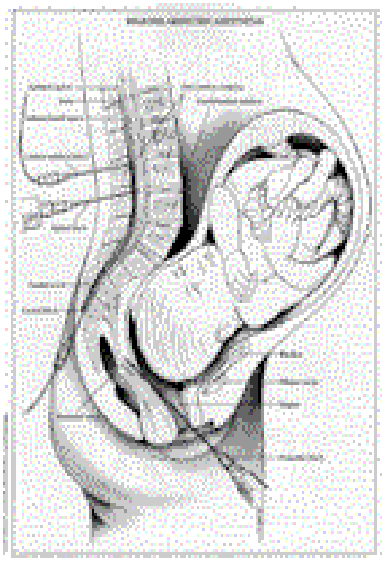
Part 1 – Advances in Patient Care

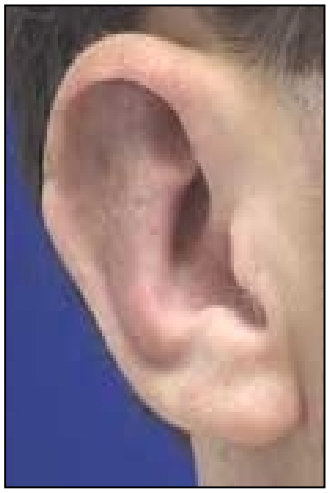
Last year the Office of Device Evaluation (ODE) approved and cleared thousands of devices used to diagnose and treat a wide variety of medical conditions. For a complete listing of newly approved devices, please see Part 2 – INDUSTRY INFORMATION. A new Premarket Approval Application (PMA) approval website describing recently approved devices with patient information is now available at http://www.fda.gov/cdrh/mda/index.html. Below we highlight several medical devices approved during this past fiscal year that we believe will have a major impact on patient care.

FETAL OXYGEN MONITOR -- The OxiFirst™ Fetal Oxygen Saturation Monitoring System, *Mallinckrodt, Nellcor Perinatal Business*, is a new type of fetal monitor that measures oxygen saturation in the baby's blood as a sign of fetal health during labor and delivery. The OxiFirst™ sensor is inserted into the mother's uterus and placed against the temple or cheek of the fetus. The monitor displays fetal oxygen saturation as percent of oxygen in the fetus's blood.

Oxifirst™ is used along with conventional electronic fetal monitoring when the fetal heart rate is "non-reassuring," that is, when the rate indicates that the baby may be in distress due to lack of adequate oxygen. It is intended for use only on single (not multiple) fetuses of at least 36 weeks gestation, where the "mother's water" has broken and the fetal head is in the normal, head down position for delivery.



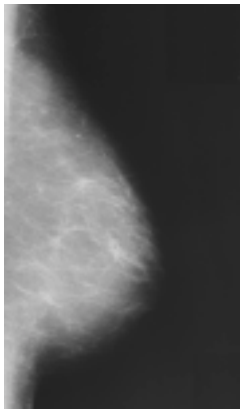
MIDDLE EAR SURGICAL IMPLANT -- The Vibrant Soundbridge, *Symphonix Devices, Inc*., is a surgically implanted hearing device intended to help adults with moderate to severe nerve hearing loss. The device is implanted behind the ear in the temporal (skull) bone. It converts sound to mechanical energy that is transferred to the middle ear. This energy vibrates delicate structures in the middle ear very much the way normal sound does. The brain interprets the vibrations as sound. During implant surgery, the surgeon implants a receiver behind the ear. A wire leads from the receiver to a small electromagnet attached to one of the middle ear bones. As an alternative to traditional hearing aids, adults with a moderate to severe sensorineural hearing loss may choose this device. Adults who choose this device should have already tried using appropriately fitting external hearing aids.



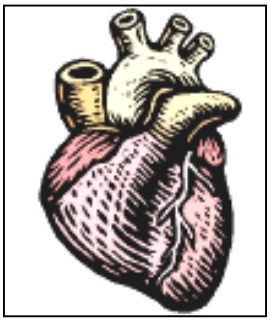
ADVANCES IN PATIENT CARE

ROBOT-ASSISTED SURGERY -- The Intuitive Surgical da Vinci Surgical System, *Intuitive Surgical Inc*., is a robotic device that enables a surgeon to perform certain types of surgery while seated at a console with a computer and video monitor. The surgeon uses handgrips and foot pedals attached to the computer console to control three robotic arms that perform the surgery using a variety of surgical tools. The robotic arms, which have a "wrist" built into the end of the surgical tools, give surgeons additional manipulation ability during minimal invasive laparoscopic surgery, enabling easier, more intricate motion and better control of surgical tools. The device is an alternative to traditional open surgery or minimally invasive manual laparoscopic surgery in an operating room environment for procedures such as gall bladder disease or gastro-esophageal reflux disease (severe heartburn).

DIGITAL MAMMOGRAPHY -- The Senographe 2000D Full Field Digital Mammography System, *General Electric Medical Systems*, is an x-ray mammography system that employs a digital receptor to capture images of the breast. These images can then be printed to film or displayed on a high-resolution workstation for interpretation by a qualified mammographer. The device passes x-rays through the breast to a receptor. In this case the receptor converts the received x-rays into digital signals that can be stored for subsequent retrieval and display. A mammographer then interprets the displayed image of the breast to determine whether the breast is normal or whether additional testing is required. This is an alternative to traditional screening and diagnostic mammography. It can be used whenever a traditional mammography examination is indicated.

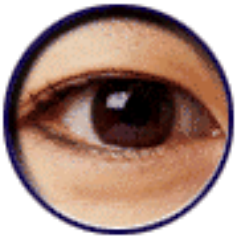


MAPPING THE HEART AND TREATING ARRHYTHMIA – The NAVI-STAR® Diagnostic/Ablation Deflectable Tip Catheter, *Biosense Webster, Inc*., is a steerable, multi-electrode catheter with a deflectable tip. The catheter provides information for electrophysiological mapping of the heart and transmits RF (radiofrequency) current through the catheter tip electrode for ablation purposes. When used with the CARTO® system and REF-STAR® reference device, a real-time 3D reconstruction of the heart chamber is provided. For ablation, the catheter is used in conjunction with a compatible RF generator and a commercially available dispersive pad. The NAVI-STAR® catheter is available with either a thermocouple or thermistor



temperature sensor embedded in the tip electrode. A magnetic field location sensor (location sensor) embedded in the tip transmits location information to the CARTOsystem. Thermal energy is delivered at the site of application, which produces a lesion that interrupts a defective electrical conduction pathway in the cardiac wall. The device and its related accessory devices are indicated for catheter-based atrial and ventricular cardiac mapping, and for cardiac ablation procedures.

LASER-BASED EYE SURGERY – The Hyperion LTK System, *Sunrise Technologies, International, Inc*., is a new type of refractive surgical laser used in the temporary reduction of hyperopia (farsightedness). Its benefit is temporary because the amount of farsightedness correction decreases over time. However, some patients may retain some or all of the correction. LTK (Laser Thermal Keratoplasty) is a surgical treatment for farsightedness performed using a holmium YAG laser. The laser produces a beam that is positioned outside of the optical zone of the eye. The beam heats the tissue in the cornea, causing it to shrink slightly. When the tissue shrinks, the cornea angle becomes steeper. This allows incoming light to focus on the retina, giving clearer images. The goal of LTK is to improve the patient's ability to see objects at a distance.



This device may be used to treat patients who have farsightedness between +0.75 to +2.5 diopters (D), who are at least 40 years of age, and whose visual acuity has changed very little over time (that is, the patient's glasses prescription has changed no more than 0.50 diopter in the previous six months). Treatment using this device will allow hyperopes (farsighted persons) who have difficulty seeing clearly at a distance without glasses to have improved distance vision without needing glasses.

TREATING GASTROESOPHAGEAL REFLUX DISEASE -- The CSM Stretta System, *Conway Stuart Medical, Inc*., is an electrosurgical system that includes a generator, electrosurgical catheter and a dispersive electrode. The electrosurgical catheter has a tip with individual needle prongs, which can be placed interstially into soft tissue to produce soft tissue coagulation. This system is intended for the treatment of Gastroesophageal Reflux Disease (GERD). The catheter tip needles are inserted into the soft tissue of the esophagus at the junction of the esophagus and stomach. Controlled energy is applied for a predetermined amount of time to produce soft tissue coagulation at the insertion site. This coagulation results in a shrinkage of the esophageal tissue at this site resulting in a narrowing of the junction which causes a reduction or elimination of stomach reflux of stomach acid up into the esophagus. This treatment can be used as an alternative to the previous surgical option of fundoplication.

Fundoplication requires use of general anesthesia, a long recovery period and an extended hospital stay since it is major abdominal surgery. The Stretta process does not require general anesthesia and has significantly less recovery time or hospital stay time. Both of these procedures are used only after patients have failed more conservative treatments for GERD such as lifestyle changes, changes in diet, and use of medication to reduce production of stomach acid. Use of this surgical procedure can, in some patients, result in total elimination of reflux and use of GERD medications, and in other patients, surgery can result in improved pH values showing reduced acid problems and consequently allowing patients to use less costly or less potent GERD medications.

FDA Consumer Web Sites

Device Databases

Center for Devices and Radiological Health (CDRH) maintains searchable databases of devices previously approved for marketing or declared substantially equivalent to a legally marketed device at http://www.fda.gov/cdrh/mda/mda-databases.html.

Consumer Information

The Consumer Staff in FDA's Center for Devices and Radiological Health, Division of Small Manufacturers Assistance also provides information to consumers regarding medical devices and radiation-emitting products to enhance their 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.shtml
E-Mail: dsma@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

The FDA Breast Implant website for consumer information is available at http://www.fda.gov/cdrh/breastimplants/index.html.

A new CDRH website entitled LASIK Eye Surgery: Learning About LASIK is available at http://www.fda.gov/cdrh/lasik/.

Part 2 – Industry Information

ODE reviews four types of marketing applications: Premarket Notification (or a 510(k) submission), Premarket Approval Application (PMA), Product Development Protocol (PDP), and Humanitarian Device Exemption (HDE). Most devices are cleared for marketing through the 510(k) process. PMAs apply to the highest risk and newly developed devices.

During Fiscal Year 2000, ODE approved 43 PMAs and 6 HDEs. These are listed below. We recommend turning to the new PMA approval website, which is available at http://www.fda.gov/cdrh/mda/index.html, for easy-to-understand one pagers for each PMA approved.

Original PMA/HDE Approvals for Fiscal Year 2000

25-Oct-99	P990033	Ceramed Corp.	PEPGEN P-15 Bone Filling Augmentation Material
12-Nov-99	P980008	LaserSight	LaserScan LSX for PRK myopia
12-Nov-99	P990014	Bausch & Lomb Surgical, Inc.	Hydroview Composite Hydrogel Foldable Ultraviolet (UV) -Absorbing Posterior Chamber Intraocular Lens (IOL)
19-Nov-99	P990010	VISX	VISX Star S2 for LASIK myopia plus astigmatism
03-Dec-99	P990019	DUSA Pharmaceuticals, Inc.	Photodynamic Therapy
03-Dec-99	P990009	Fusion Medical Technologies, Inc.	Hemostatic Agent
07-Dec-99	H990007	CryoLife, Inc.	BioGlue®Surgical Adhesive
10-Dec-99	H980006	DataMedix Corp.	Therasphere®
16-Dec-99	P970049	Dishler	Dishler Excimer for LASIK myopia plus astigmatism
07-Jan-00	P990016	McCue Corp., Inc.	Ultrasonic Bone Sonometry System
20-Jan-00	P990035	Sunlight Ultrasound Technologies, Inc.	Ultrasonic Bone Sonometry System
28-Jan-00	P990066	GE Medical System	Senographe 2000D (1st digital mammography)

01-Feb-00	H990011	Nitinol Medical. Technologies, Inc	CardioSEAL® Septal Occlusion System
03-Feb-00	P980040	Allergan, Inc.	Sensar Soft Acrylic UV-Absorbing Posterior Chamber IOL
23-Feb-00	P990027	Bausch & Lomb	Technolas 217A for LASIK myopia
24-Feb-00	P990023	Alcon Laboratories	Cellugel Ophthalmic Viscosurgical Device
09-Mar-00	H990008	Interpore Cross International	Telescopic Plate Spacer (TPS) Spinal System
17-Mar-00	P990054	Cardiac Pathways Corp.	CHILLI COOLED ABLATION SYSTEM with Tracking
31-Mar-00	H990014	Medtronic, Inc.	Gastric Electrical Stimulation System (Now known as Enterra Therapy System)
02-Apr-00	P990013	Star Surgical, Co.	IOL
12-Apr-00	P990048	Carl Zeiss	VISULAS 690s Laser and VISULINK PDT adapter
12-Apr-00	P990049	Coherent Medical Group	Coherent Opal Photoactivator and modified Coherent LaserLink
18-Apr-00	P950020	Interventional Technologies, Inc.	Cutting Balloon
10-May-00	P990074	McGhan Medical Corp.	RTV Saline-Filled Breast Implant
10-May-00	P990075	Mentor Corporation	Saline-Filled and Spectrum® Mammary Prosthesis
11-May-00	H990012	Cardiovascular Diagnostics, Inc.	TAS Ecarin Clotting Time Test
12-May-00	P990053	Nellcor Puritan Bennett, Inc.	Oxifirst™ Fetal Oxygen Saturation Monitor
26-May-00	P990028	Focal Inc.	FocalSeal-L Synthetic Absorbable Surgical Sealant
31-May-00	P990071	Biosense Webster, Inc.	Stockert 70 RF Generator for Cardiac Ablation
13-Jun-00	P990030	Cohesion Technologies, Inc.	CoStasis Surgical Hemostar

14-Jun-00	P980050	Medtronic, Inc.	Medtronic® Jewel® AF 7250 Dual Chamber Implantable Cardioverter Defibrillator, Model 9961 Programmer Application Software and Medtronic® Sprint™ Model 6943 Steroid Eluting, Screw-in, Atrial/Ventricular Lead
15-Jun-00	P990025	Biosense Webster, Inc.	NAVI-STAR® Diagnostic/Ablation Deflectable Tip Catheter
22-Jun-00	P990037	Vascular Solutions, Inc	Vascular Solutions Duett™ Sealing Device
30-Jun-00	P990021	QLT Photo Therapeutics, Inc.	Diomed 630 PDT Laser, Model T
30-Jun-00	P990078	Sunrise	Hyperion LTK for hyperopia
11-Jul-00	P990018	Menicon U.S.A.	Minicon™ (tisilfocon A) Rigid
14-Jul-00	P990064	Medtronic, Inc.	MOSAIC® Porcine Bioprosthesis, Models 301 and 310
21-Jul-00	P990034	Medtronic, Inc.	Medtronic Isomed Infusion System
24-Jul-00	P000006	Mentor Corp.	Alpha I Inflatable Penile Prosthesis
01-Aug-00	P990039	Metra Biosystems	QUS-2 Calcaneal Ultrasonometer
22-Aug-00	P990072	Westcon Contact Lens Co., Inc.	Horizon 55 EW and Horizon 55
31-Aug-00	P990052	Symphonix Devices, Inc.	Vibrant P Soundbridge System
05-Sep-00	P970042	Medstone International, Inc.	Medstone STS™ Lithotripter
08-Sep-00	P990055	Bayer Corp.	Bayer Immuno 1 Complexed PSA Assay
19-Sep-00	P980010	Ostenometer MediTech, Inc.	DTU-one Ultrasound Scanner
25-Sep-00	P990040	Cordis Neuro-vascular Inc.	TRUFILL®n-Butyl Cyanoacrylate (nBCA) Liquid Embolic System
29-Sep-00	P000014	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products:Anti-HBS Reagent Pack/Anti-HBS Calibrators

29-Sep-00	P000009	Biotronik, Inc.	Phylax AV Implantable Cardioverter Defibrillator with Program Software (I-GAV.2.U)
29-Sep-00	P000011	Biocompatibles Cardiovascular, Inc.	Bio*divYsio*™ AS PC (phosphorylcholine) Coated Stent and Delivery System

Significant Medical Device Breakthroughs

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 00. 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.

Devices Approved via PMA/HDE

Division of Cardiovascular and Respiratory Devices (DCRD)

Medtronic® Jewel® AF 7250 Dual Chamber Implantable Cardioverter Defibrillator by Medtronic, Inc. (June 14, 2000)

NAVI-STAR® Diagnostic/Ablation Deflectable Tip Catheter by Biosense Webster, Inc. (June 15, 2000)

Division of Clinical Laboratory Devices (DCLD)

TAS Ecarin Clotting Time Test by Cardiovascular Diagnostics, Inc. (May 11, 2000)

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

RTV Saline-Filled Breast Implant by McGhan Medical Corp. (May 10, 2000)

Saline-Filled and Spectrum® Mammary Prosthesis by Mentor Corporation (May 10, 2000)

FocalSeal-L Synthetic Absorbable Surgical Sealant by Focal Inc. (May 26, 2000)

Apligraf® (Graftskin) by Organogenesis Inc. (June 20, 2000)

TRUFILL® n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System by Cordis Neurovascular Inc. (September 25, 2000)

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

Hyperion® for Laser Thermal Keratoplasty for Hyperopia (+0.75 to +2.5 diopters) by Sunrise Technologies (June 30, 2000)

Vibrant Soundbridge by Symphonix Devices, Inc. (August 31, 2000)

Division of Reproductive, Abdominal and Radiological Devices (DRARD)

Senographe 2000D (1st digital mammography) by GE Medical System (January 28, 2000)

Gastric Electrical Stimulation System by Medtronic, Inc. (March 31, 2000)

Oxifirst™ Fetal Oxygen Saturation Monitor by Nellcor Puritan Bennett, Inc. (May 12, 2000)

Alpha I Inflatable Penile Prosthesis by Mentor Corp. (July 14, 2000)

Medstone STS™ Lithotripter by Medstone International, Inc. (September 5, 2000)

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

DCLD

Becton, Dickinson & Co.'s Probetec ET System for Chlamydia Trachomatis and Gonorrhea (November 4, 1999)

Wallac Neonatal Biotinidase Test Kit by Perkin Elmer Inc. (November 22, 1999)

Axix %CDT Turbidometric Immunoassay by Axis (December 21, 1999)

MTM Bioscanner HDL Test Strips (Over-the-Counter) by Polymer Technology Systems, Inc. (January 13, 2000)

CDC's Synthetic VDRL Antigen Slide for Syphilis (February 23, 2000)

Cedia Dau Amphassure Assay by Microgenics Corporation (May 2, 2000)

BV Blue by Gryphus Diagnostics, L.L.C. (May 15, 2000)

Bioscanner Triglycerides Test Strips by Polymer Technology Systems, Inc. (May 24, 2000)

DGRND

Microwave Delivery System (MDS), Model MMC-3000 by Microwave Medical, Inc. (October 1, 1999)

600 C Laser Keratome by IntraLase Corporation (December 17, 1999)

Excimer Laser Phototherapy System AL7000 by AccuLase, Inc. (January 27, 2000)

Visage Cosmetic Surgery Model V5000 by ArthroCare Corporation (March 20, 2000)

CSM Stretta System by Conway Stuart Medical Inc. (April 18, 2000)

Laser Photolysis System and Pharo Opthalmic Surgery System by A.R.C. Laser Corporation (June 29, 2000)

da Vinci™ Endoscopic Instrument Control System and Endoscopic Instruments by Intuitive Surgical, Inc. (July 11, 2000)

DOED

Purilens System contact lens cleaning and disinfection system by Purilens, Inc. (October 1, 1999)

Ocu-flex-38 Keratoconus (polymacon) soft contact lens by Ocu-Ease Optical Products, (October 4, 1999)

Hylashield CL contact lens lubricating eye drop by Biomatrix, Inc. (March 2, 2000)

Hylasine, hylan B Gel by Biomatrix, Inc. (March 13, 2000)

VISX WaveScan Wavefront Analysis System Refractometer (April 28, 2000)

Autononmous Technologies CustomCornea Wavefront Analysis Refractometer (May 16, 2000)

Sportsight GP rigid gas permeable contact lens by Paragon Vision Sciences, (May 22, 2000)

Option care system for cleaning and disinfecting non-UV absorbing contact lenses by Optisonic, Inc. (June 5, 2000)

MeroGel Otologic pack by Medtronic Xomed (July 3, 2000)

DRARD

LifeSite® Hemodialysis Access System by Vasca, Inc. (August 24, 2000)

ODE Guidance Documents

The following guidance documents were adopted by ODE and its operating divisions during FY 00 and are available from the Division of Small Manufacturers Assistance (DSMA, HFZ-200). To contact DSMA, call 800-638-2041 or 301-443-6597; fax 301-443-8818; Email dsma@cdrh.fda.gov or write to DSMA (HFZ-200, Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307.)

Many are also available through the CDRH Facts-On-Demand (faxback service at 800-899-0381 or 301-837-0111) and the World Wide Web (CDRH homepage: http://www.fda.gov/cdrh) which provide easy access to the latest information and operating policies and procedures.

ODE

Use of Standards in Substantial Equivalence Determinations (March 13, 2000)

DCLD

Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s (July 22, 2000)

Guidance for Over-the-Counter (OTC) Ovulation Predictor 510(k)s (July 22, 2000)

Class II Special Control Guidance Document for Anti-Saccharomyces cerevisia (S. cerevisiae) Antibody (ASCA) Premarket Notification (August 23, 2000)

DCRD

Guidance for Cardiovascular Intravascular Filter Submissions (November 26, 1999)

Guidance for Annuloplasty Rings 510(k) Submissions (November 26,1999)

Guidance for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer (January 24, 2000)

Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions (February 21, 2000)

Guidance for Electrical Safety, Electromagnetic Compatibility, Mechanical Testing for Indwelling Blood Gas Analyzer Premarket Notification Submissions (June 28, 2000)

Class II Special Control Guidance for Acute Upper Airway Obstruction Devices (July 3, 2000)

One Consolidated Annual Report for a Device Product Line (1-CARD): Pilot for Preparation of Annual Reports for Pacemaker Premarket Approval Applications (July 6, 2000)

Draft Guidance for Infant/Child Apnea Monitor 510(k) Submissions (September 22, 2000)

DGRND

Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses (October 5, 1999)

Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery (December 16, 1999)

Guidance Document for the Preparation of IDEs for Spinal Systems (January 13, 2000)

Guidance for Surgical Suture 510(k)s (August 10, 2000)

Guidance for Spinal System 510(k)s (September 27, 2000)

DOED

Intraocular Lens Guidance Document (draft) (October 14, 1999)

Guidance for Premarket Submissions of Orthokeratology Rigid Gas Permeable Contact Lenses (April 10, 2000)

Refractive Implants: Guidance for Investigational Device Exemptions (IDE) and Premarket Approval (PMA) Applications (draft) (August 1, 2000)

DRARD

Draft Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery (December 16, 1999)

Guidance for the Content of Premarket Notifications for Penile Rigidity Implants; Final (January 16, 2000)

Class II Special Controls Guidance Document for Clitoral Engorgement Devices (July 3, 2000)

Guidance for the Submission of Premarket Notifications for Medical Image Management Devices (July 27, 2000) (update of PACS guidance, DSMA FOD#416)

Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources (August 2, 2000)

Draft Guidance Documents on the Internet for Comment Purposes Only

Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) that are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease (October 8, 1999)

Guidance on the Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing (December 21, 1999)

Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices (March 8, 2000)

Revision to the Extracorporeal Shockwave Lithotripter Guidance (August 9, 2000)

Guidance for Administrative Procedures for CLIA Categorization (August 14, 2000)

Part 3 – Key Performance Indices

ODE is 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 review activities and performance for Fiscal Year 2000 (FY 00). Most of the data below can be found in the tables in Part 5 -- the Operational Summary section of this report. 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 section deals with Humanitarian Device Exemptions (HDEs), Investigational Device Exemptions (IDEs), and Premarket Notifications (510(k)s).

Workload/Resources

During FY 00, ODE received a total of 16,919 submissions, compared to 16,812 in FY 99; 9,774 were major submissions compared to 9,792 last fiscal year [see Table 1]. Major submissions include: IDEs -- originals, amendments and supplements; PMAs -- originals and supplements; HDEs -- originals and supplements; and 510(k)s. Other submissions include PMA amendments and reports; master files; and 510(k) amendments and supplements.

Table 1. Major Submissions Received
FY 90 – FY 00

Type of Submission	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Orig. PMAs	79	75	65	40	43	39	44	66	47	60	67
PMA Supp.	660	593	606	395	372	499	415	409	513	552	545
Orig. IDEs	252	213	229	241	171	214	253	297	322	304	311
IDE Amend.	288	283	297	320	254	210	219	223	226	275	240
IDE Supp.	3,043	3,647	3,644	3,668	3,020	3,171	3,189	3,776	4,277	4,127	4,388
510(k)s	5,831	5,770	6,509	6,288	6,434	6,056	5,297	5,049	4,623	4,458	4,202
Orig. HDE	0	0	0	0	0	0	0	4	8	12	11
HDE Supp.	0	0	0	0	0	0	0	0	0	4	10
Total	**10,153**	**10,581**	**11,350**	**10,952**	**10,293**	**10,189**	**9,417**	**9,824**	**10,016**	**9,792**	**9,774**

On the decision side, ODE completed the processing of 9,994 major submissions, compared to 9,881 major submissions in FY 99. [See Table 2 for major submissions completed.]

Table 2. Major Submissions Completed
FY 90 - FY 00

Type of Submission	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Orig. PMAs	47	27	12	24	26	27	43	48	46	45	43
PMA Supp.	700	479	394	354	385	435	462	401	421	437	474
Orig. IDEs	248	220	215	248	174	210	260	272	325	305	320
IDE Amend.	270	287	297	324	256	213	218	220	225	268	251
IDE Supp.	2,968	3,705	3,469	3,814	3,070	3,181	3,121	3,777	4,209	4,224	4,335
510(k)s	6,197	5,367	4,862	5,073	7,135	7,948	5,563	5,155	5,229	4,593	4,397
Orig. HDE	0	0	0	0	0	0	0	2	4	6	6
HDE Supp.	0	0	0	0	0	0	0	0	0	3	10
Total	**10,430**	**10,085**	**9,249**	**9,837**	**11,045**	**12,014**	**9,667**	**9,875**	**10,459**	**9,881**	**9,994**

ODE ended the fiscal year with 359 employees. During the year, 27 full-time employees (12 scientific reviewers, 1 medical officer, 13 clericals and 1 program analyst) left through resignation or retirement. During FY 00, 52 new employees (30 scientific reviewers, 6 medical officers, 1 program analyst, 11 clericals, and 4 summer students) joined our office.

Premarket Approval Applications (PMAs)

[NOTE: In previous annual reports, the PMA data included data for Humanitarian Device Exemption (HDE) Applications. This annual report contains a separate section for HDEs (see page 19). We also added new statistical Tables 8, 9 and 10 that contain HDE data.]

ODE received 67 complete original PMAs (7 more than the number received in FY 99) and 55 modular submissions representing 48 PMA shells.

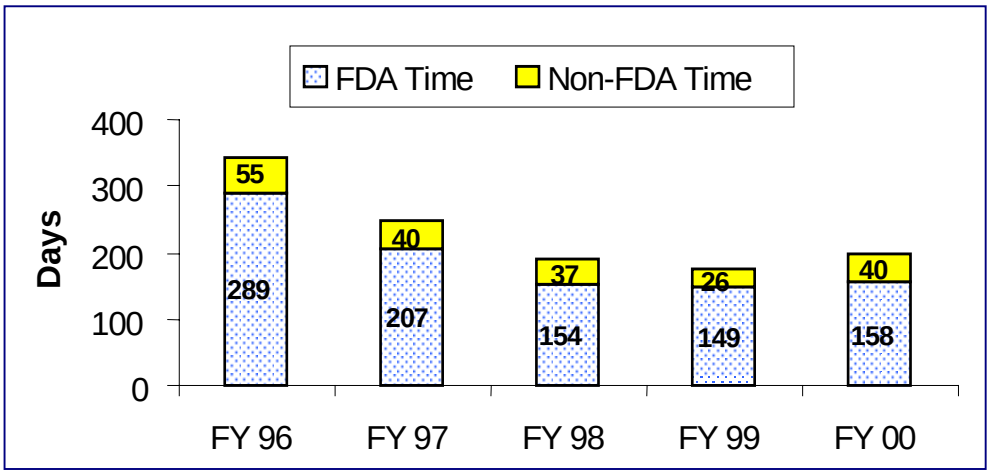
The total number of PMAs in inventory (active and on hold) at the end of this fiscal year decreased from 77 in FY 99 to 76. The number of active PMAs under review decreased at the end of FY 00 to 35 compared to 47 last year, and those on hold increased from 30 in FY 99 to 41 in FY 00. This means that we took action on more PMAs and thus reduced the number under active review. For the third consecutive year, there were no active and overdue PMAs at the end of the fiscal year.

The total number of PMA actions increased from 229 to 321 actions. These actions included 68 filing decisions, 173 review determinations, and 80 approval/approvable/not approvable decisions.

The 80 original PMA decisions were comprised of 43 approved PMAs, 33 approvable PMAs, and 4 not approvable PMAs. None of the 43 approvals were expedited PMAs. See Part 2 (INDUSTRY INFORMATION) for a complete list of PMA approvals.

Average FDA review time for original PMAs reaching approval increased from 149 days in FY 99 to 158 days in FY 00. The non-FDA component of review time increased from 26 days in FY 99 to 40 days this fiscal year. Thus, the total average review time increased to 198 days. Of greater significance to industry is the total elapsed time from submission to decision.

Figure 1. Average Review Time for PMA Decision Cohort Approvals



In FY 00, the total average elapsed time for PMA decision cohort performance decreased from 380 days in FY 99 to 362 days in FY 00. (Please refer to Table 4.)

Figure 2. Original Receipt Cohort PMAs Received and Filed

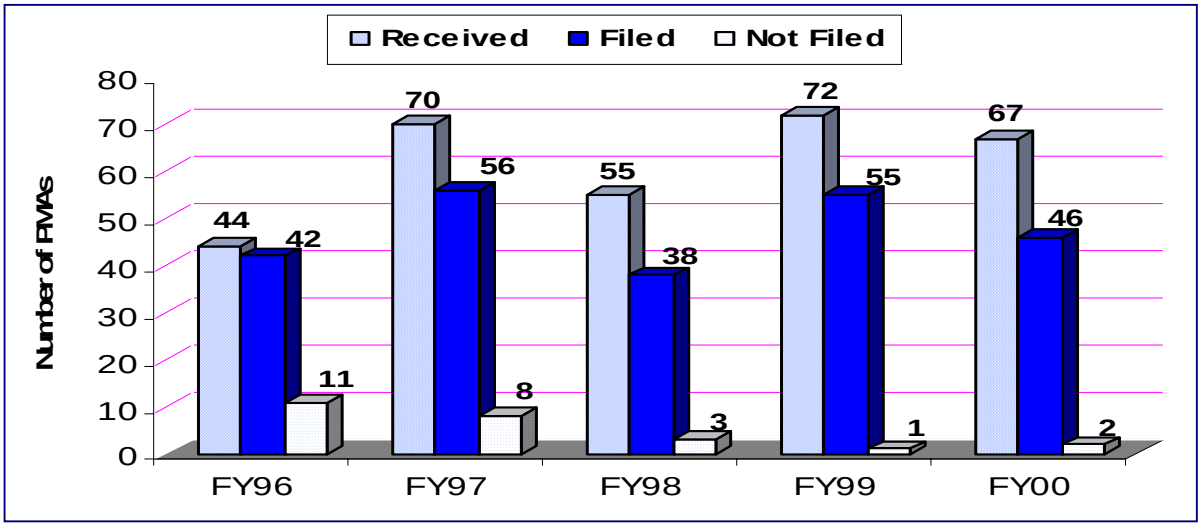
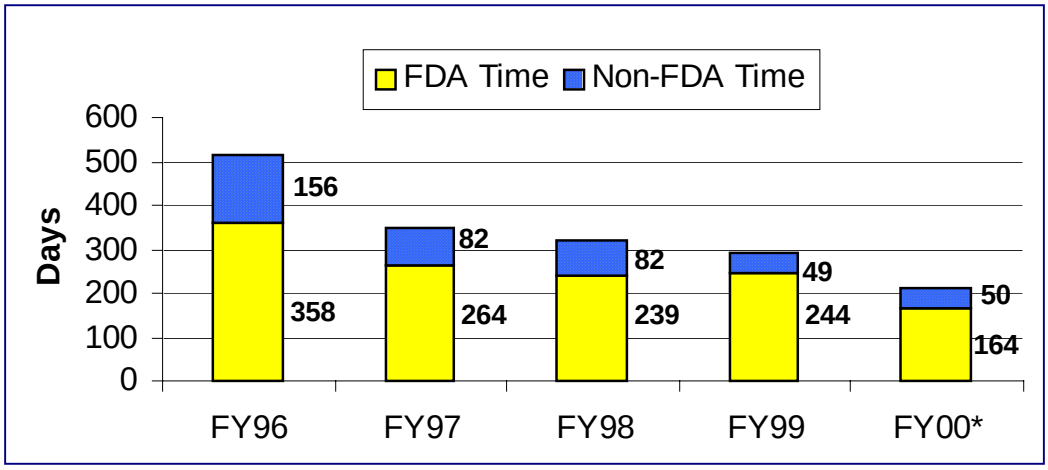


Figure 3. Receipt Cohort PMA Average Elapsed Time from Filing to Final Action



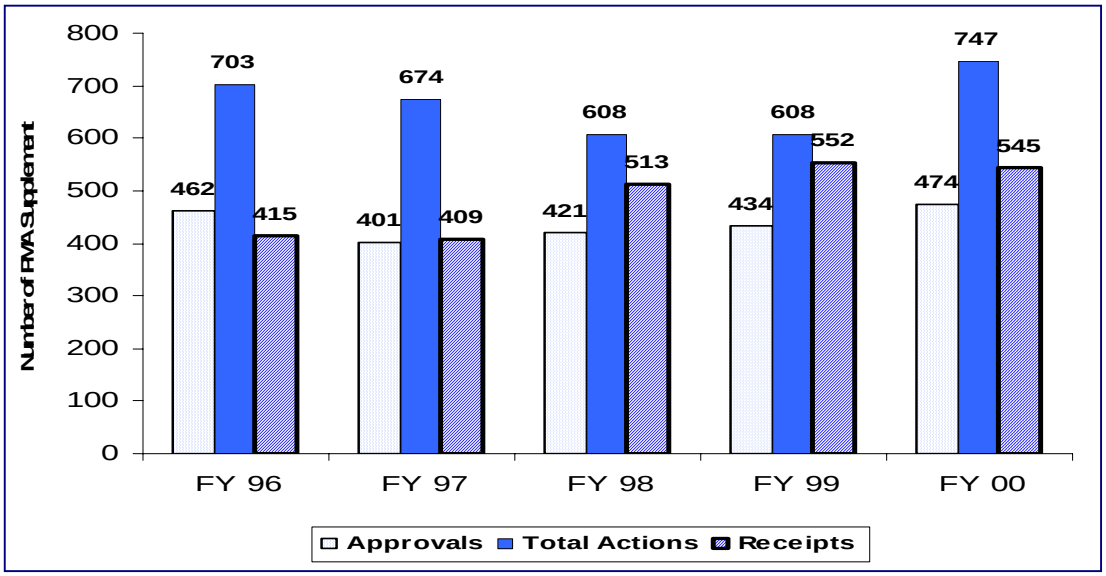
*First six months

For the first 6 months of FY 00 for PMA receipt cohort performance, the average FDA days from filing to first action decreased from 145 in FY 99 to 139 days.

The average FDA (total) elapsed time to an approval or to a denial decreased from 244(293) in FY 99 to 164(214) days in FY 00. The median FDA (total) elapsed time to an approval or denial decision decreased from 240(269) in FY 99 to 178(211) days in FY 00. This means that all of the statistics of the PMA receipt cohort for FY 00 indicate that we are making decisions faster.

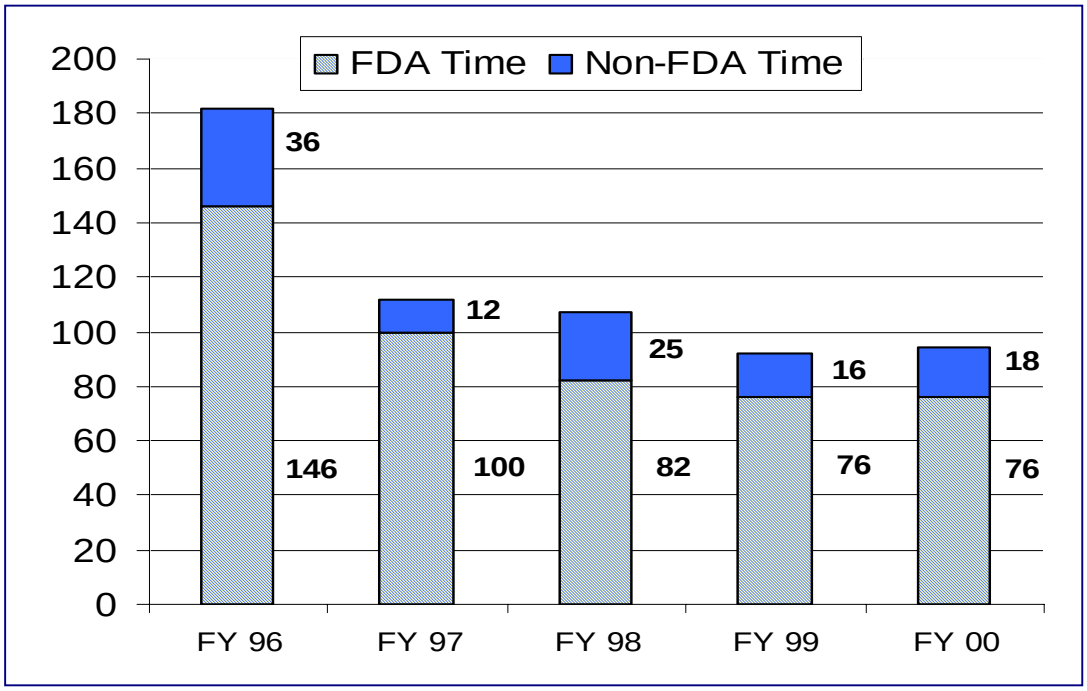
The number of PMA supplements received decreased from last year's 552 to 545. There were 747 PMA supplement actions which is up from last year's 608 total actions. These actions included 17 panel track PMA supplement filing decisions, 98 scientific review decisions, and 632 approval decisions.

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



For PMA supplements reaching final action, the average elapsed FDA review time increased from 92 days in FY 99 to 94 days in FY 00, and the total average elapsed time increased from 118 days to 122 days.

Figure 5. Average Review Time for PMA Supplements



Just as in FY 97, FY 98 and FY 99, there were no PMA supplements active and overdue at the end of this fiscal year. The number of active supplements decreased to 98 in FY 00 from 158 in FY 99, while the number of supplements on hold increased from 69 to 84. This means that although we are receiving about the same number of PMA supplements, we are reaching final decisions on more, but we are taking an average of 3 extra days for the decisions.

For the first 6 months of FY 00 for PMA supplements receipt cohort performance, the first action and final action as follows. The average FDA days from filing to first decision decreased from 74 in FY 99 to 67 days in FY 00. The average FDA (total) elapsed time to an approval or denial decreased from 79(95) in FY 99 to 66(76) in FY 00. The median FDA (total) elapsed time to an approval or denial remained the same from 35(47) in FY 99 to 35(43) days in FY 00.

Real-Time Review of PMA Supplements

A total of 146 requests were received and processed for real time PMA supplements in FY 00 which represents 27% of all supplements received. Of those submissions, 134 were approved. Most applicants chose telephone conferencing versus a face-to-face

meeting or a videoconference. The majority of these applications were reviewed in DCRND (54%) followed by DGRD (23%), DOD (11%), DRAERD (8%), DDIGD (2%) and DCLD (1%). Overall, average review time from "receipt" to first action (approvable, not approvable or approval order) was 34 days, and was 38 days from receipt to approval.

Product Development Protocols (PDPs)

Two PDPs have been approved in FY 00, and reports are being received on their progress for the clinical study. No original Notices of Completion were declared complete. In addition, five "Real Time" supplements, and three routine PDP supplements were approved. Note that a PDP that has been declared complete is considered to have an approved PMA. ODE continues to encourage the use of the PDP process and will work with the interested applicants to fully evaluate their PMA options.

Modular PMA Review

ODE received a total of 48 PMA shells and 55 modules. A total of 17 modules were found to be acceptable while 12 received deficiency letters. A number of modules were rolled into PMA review during FY 00 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. Review times for PMAs that had modular submissions were approximately half that for traditional PMAs. 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 received 11 original HDEs, 1 less than the number received in FY 99. The total number of original HDE actions decreased from 37 in FY 99 to 36 in FY 00. These actions included 12 filing decisions, 16 review determinations, 7 approval decisions and 1 other final decision.

A total of 8 first actions were made this fiscal year, a decrease from 13 made last year. The average time from filing to first action decreased from 87 days in FY 99 to 61 days in FY 00.

One hundred percent of the first actions made in FY 00 occurred within 75 days.

The 7 approval decisions were comprised of 6 approved HDEs and 1 approvable HDE.

In FY 00, the average elapsed time (from filing to final approval) for original HDEs was 216 days, an increase from 163 days in FY 99. The average FDA time was 112 days, a decrease from 113 days in FY 99. The average non-FDA time was 104 days, a significant increase from 50 days last year.

The total number of original HDEs in inventory (active and on hold) at the end of this fiscal year was 10, the same as last fiscal year. Of these, 2 were under review and 8 were on hold. There was no active HDEs that were overdue at the end of the fiscal year.

The number of HDE supplements received increased from 4 in FY 99 to 10 in FY 00. There were 11 HDE supplement actions in FY 00, up from 7 in FY 99. These actions included 10 approval decisions and 1 not approvable decision.

A total of 10 first actions for HDE supplements were made this fiscal year, an increase from 4 last year. The average time from filing to first action decrease from 57 days in FY 99 to 44 days in FY 00. One hundred percent of the first actions were made within 75 days.

The average elapsed time (from filing to final approval) for HDE supplements decreased from 94 days in FY 99 to 76 days in FY 00. The average FDA time decreased from 70 days in FY 99 to 43 days in FY 00. Non-FDA time increased from 24 days in FY 99 to 33 days in FY 00.

The number of HDE supplements in inventory (active and on hold) at the end of this fiscal year was 1, the same as last fiscal year.

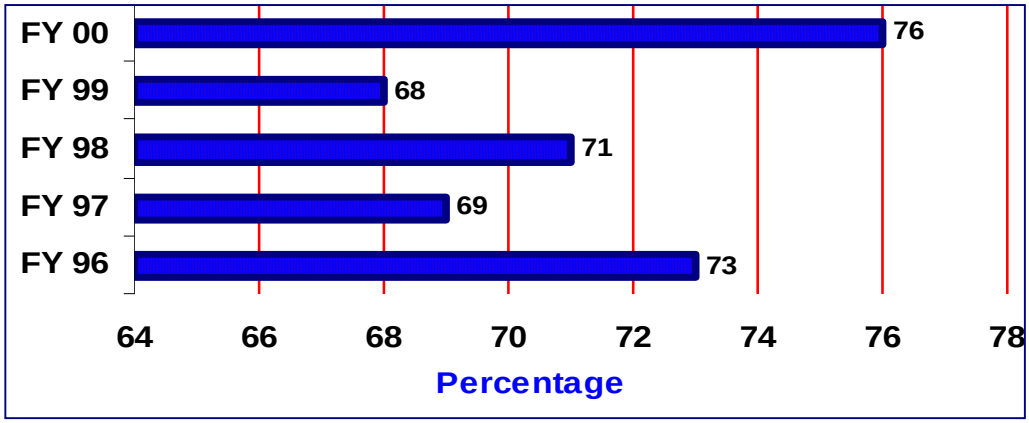
Investigational Device Exemptions (IDE)

During FY 00, ODE reviewed 244 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 phone.

ODE received 311 original IDEs, an increase from 304 received in FY 99. There were 320 decisions made on original IDEs, an increase from 305 last year.

Ninety-nine percent of all original IDE decisions were issued within 30 days in FY 00. The average review time was 28 days.

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



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

Of the IDEs which were complete enough to support substantive review, the percentage of IDEs approved on the first review cycle increased from 68% in FY 99 to 76% in FY 00.

During this fiscal year, 240 IDE amendments were received. Decisions were made on 251 amendments: 107 approvals (43%); 34 disapprovals (13%); and 110 other administrative actions (44%). One hundred percent of these decisions were made within 30 days.

It took an average total time of 136 days to approve IDEs that were initially disapproved, down from 145 days in FY 99. This average approval time consisted of 70 days for FDA time, up from 57 days last year, and 66 days for non-FDA time, down from 88 days in FY 99.

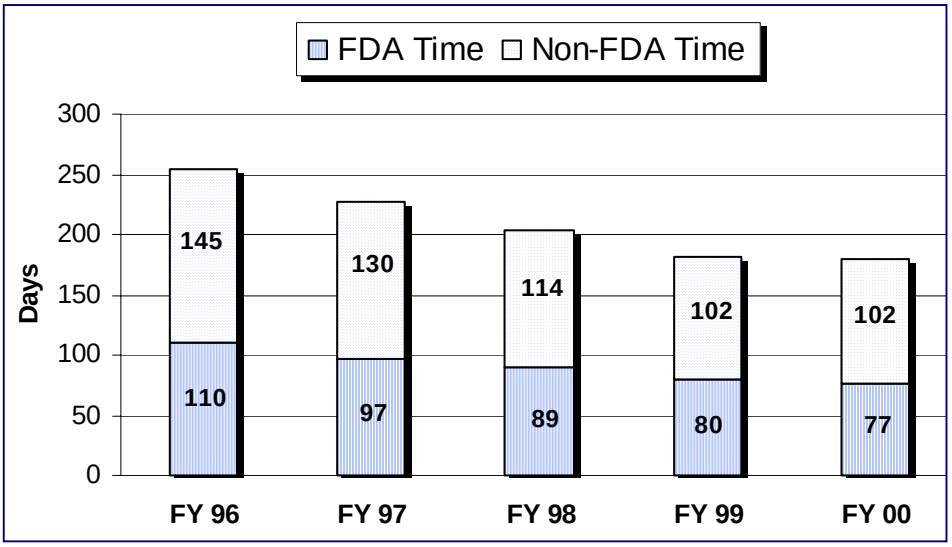
ODE received 4,388 IDE supplements during FY 00. There were no overdue supplements at the end of the year, and the percentage of supplements reviewed within the 30-day statutory timeframe was 100 percent in FY 00. The average review time for IDE supplements stayed the same at 20 days.

Premarket Notification (510(k)s)

ODE received 4,202 original 510(k)s, as well as 1,742 510(k) supplements (responses to hold letters, the receipt of which restart the 90-day review clock), and 2,953 510(k) amendments (additional information received while the 510(k) is under review, the receipt of which does not affect the review clock).

The total average review time remained at 102 days in FY 00, and the average FDA review time was 77 days, down from 80 days in FY 99. 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 a current low of 72 days in FY 00.

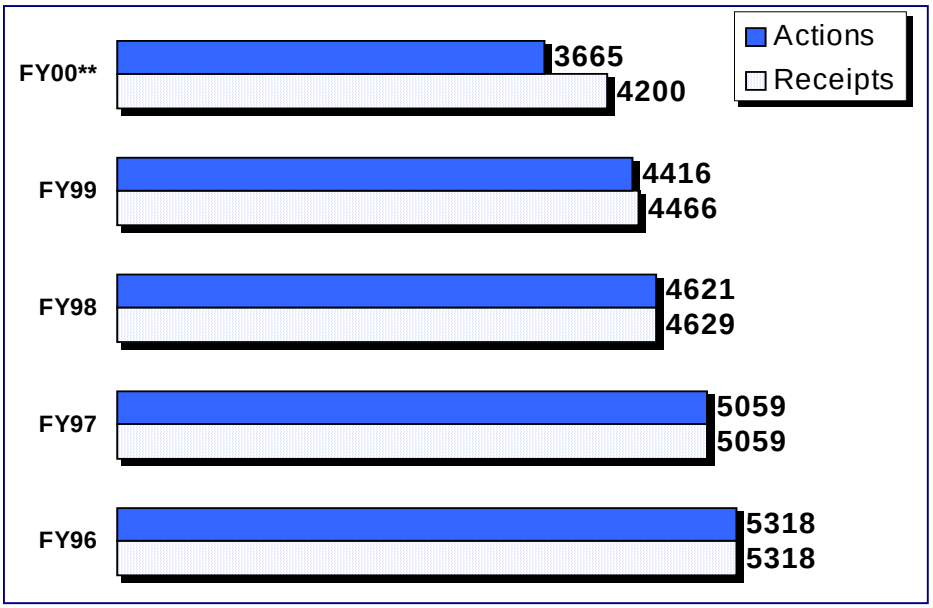
Figure 7. Average 510(k) Review Time for Decision Cohort



There were 1,220 510(k)s in inventory (those under active review or on hold) at the end of this fiscal year, which is 184 less than the 1,404 in FY 99's end-of-year inventory. The number on hold decreased from 461 at the end of FY 99 to 370. Most important, for the fifth consecutive fiscal year there was no 510(k)s active and overdue at the end of the reporting period.

For the first 9 months of FY 00 for receipt cohort performance, the FDA time from receipt to final decision decreased to 60 days compared to 66 days for the first 9 months in FY 99.

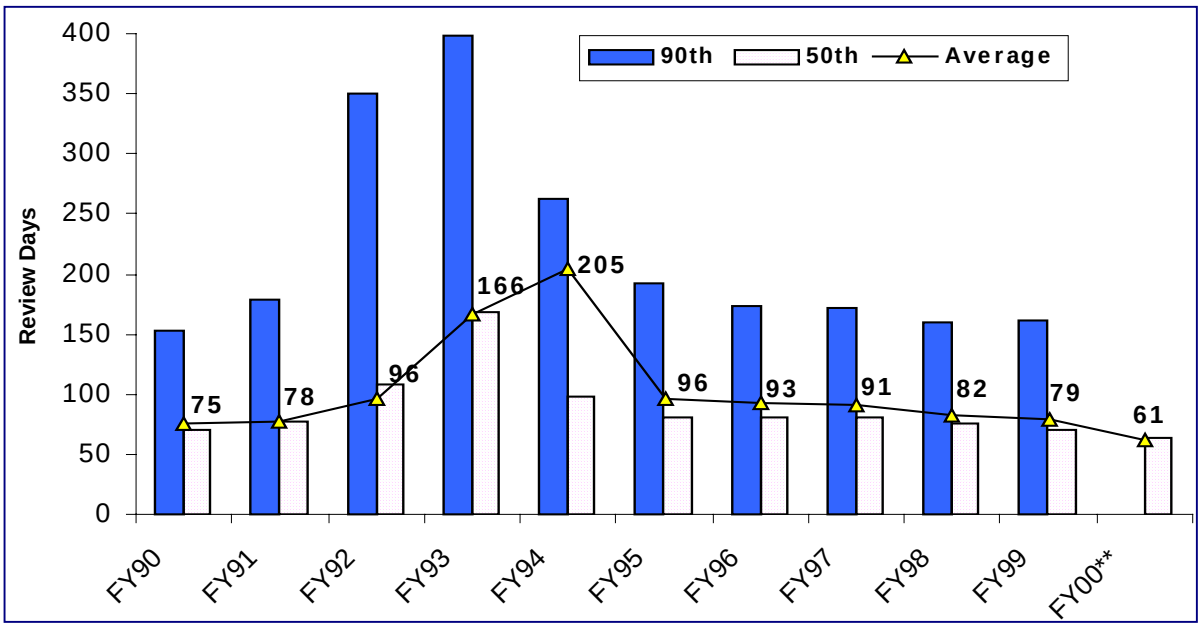
Figure 8. Receipts and Actions for 510(k) Receipt Cohorts*



*Cut Off Date of 9/30/00 for all receipt cohorts.
**12 month projection based on first 9 months of receipts.

For the first 9 months of FY 00 for receipt cohort performance, the total time from receipt to final decision decreased to 75 days compared to 77 days for the first 9 months in FY 99.

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



*Cut Off Date as of 9/30/00 for all receipt cohorts.
**For the first 9 months of FY 00. 90th percentile data not available for FY 00.

Third-Party Review of 510(k)s

During FY 00, ODE received 47 510(k)s reviewed by third-party organizations under the Accredited Persons provisions (section 523) of the Federal Food, Drug, and Cosmetic Act. This is a small percentage of all 510(k)s that were eligible for third-party review, but is a 47% increase over the number of such submissions received by ODE last fiscal year. ODE made final decisions on 46 "third-party" 510(k)s in FY 00, an increase from the 29 final decisions in FY 99. The average total elapsed time from a third party's receipt of a 510(k) to ODE's issuance of a substantial equivalence decision was 68 days, as compared to the average total elapsed time of 99 days for ODE's decision on comparable 510(k)s that did not have a third-party review.

In June 2000, to encourage greater industry use of Accredited Persons, the Center expanded the list of Class I and Class II devices that are eligible for review from 154 devices to 211 devices. In the *Federal Register* on July 18, 2000 (65 FR 44540), the Center also proposed an expansion pilot that would permit third-party review of a greatly expanded list of devices. The pilot would allow-subject to certain specified conditions-third-party review of Class II devices for which device-specific guidance does not exist.

Until now, device-specific guidance had existed for each Class II device that is eligible for third-party review. The *Federal Register* notice established a 45-day public comment period, which ended September 1, 2000. The Center has reviewed the public comments and intends to finalize the proposal in FY 01. Information on the expansion pilot is available on the Center's third party web page at http://www.fda.gov/cdrh/thirdparty.

Special 510(k)s

From October 1, 1999 to September 30, 2000 ODE received 615 *Special* 510(k)s out of the 4,202 total number of 510(k)s received, and 583 have received final decisions with the average FDA review time of 27 days and the average total time of 32 days, and 551 were found substantially equivalent and the remaining 32 had other decisions such as withdrawn or deleted.

Abbreviated 510(k)s

During the same timeframe ODE received 150 *Abbreviated* 510(k)s out of the 4,202 total number of 510(k)s received. One hundred eighteen received final decisions (104 substantially equivalent and 12 other decisions, and 2 NSEs) with a FDA average review time of 83 days and total time of 103 days. None of the *Abbreviated* 510(k)s went over 90 days.

Significant Medical Device Breakthroughs

During FY 00, ODE approved 15 PMAs and cleared 25 510(k)s that represented significant medical device breakthroughs. See INDUSTRY INFORMATION for a complete listing.

Classification Actions

- Published a proposed rule in the *Federal Register* on October 1, 1999, classifying the subcutaneous, implanted, intravascular infusion port and catheter and the percutaneous, implanted, long-term intravascular catheter into Class II.

- Published a final rule in the *Federal Register* on October 5, 1999, classifying the nonresorbable gauze/sponge for external use, the hydrophylic wound dressing, the occlusive wound dressing, and the hydrogel wound dressing into Class I.

- Published a final rule in the *Federal Register* on May 18, 2000, classifying female condoms into Class III.

- Published a final rule in the *Federal Register* on June 8, 2000, classifying liquid chemical sterilants/high level disinfectants into Class II and general-purpose disinfectants into Class I.

- Published a final rule in the *Federal Register* on June 13, 2000, classifying the subcutaneous, implanted, intravascular infusion port and catheter and the percutaneous, implanted, long-term intravascular catheter into Class II.

Automatic Evaluation of Class III Designation

- Published a final rule in the *Federal Register* on March 3, 2000, classifying the nitric oxide administration apparatus, nitric oxide analyzer, and the nitrogen dioxide analyzer into Class II.

- Published a final rule in the *Federal Register* on March 29, 2000, classifying the biotinidase test system into Class II.

- Published a final rule in the *Federal Register* on June 23, 2000, classifying devices to relieve upper airway obstruction into Class II.

- Published a final rule in the *Federal Register* on August 2, 2000, classifying the clitoral engorgement device into Class II.

- Published a final rule in the *Federal Register* on August 16, 2000, classifying the Anti-Saccharomyces cerevisiae (S. cerevisiae) Antibody (ASCA) in vitro diagnostic device into Class II.

Final Reclassification Actions

- Published a final rule in the *Federal Register* on February 2, 2000, to reclassify the penile rigidity implant from Class III to Class II.

- Published a final rule in the *Federal Register* on February 11, 2000, to reclassify and codify [Nd:YAG] laser for peripheral iridotomy from Class III to Class II.

- Published a final rule in the *Federal Register* on March 31, 2000, to reclassify 28 Preamendments Class III Devices into Class II.

- Published a final rule in the *Federal Register* on April 7, 2000, to reclassify OTC Test Sample Collection Systems for Drugs of Abuse Testing from Class III to Class I.

- Published a final rule in the *Federal Register* on April 11, 2000, to reclassify cardiopulmonary bypass accessory equipment, goniometer device, and electrode cable devices from Class I to Class II.

- Published a final rule in the *Federal Register* on April 13, 2000, to reclassify the stainless steel suture into Class II.

- Published a final rule in the *Federal Register* on April 18, 2000, to reclassify the nonabsorable expanded polytetrafluoroethylene suture into Class II.

- Published a final rule in the *Federal Register* on August 3, 2000, to reclassify the extracorporeal shock wave lithotripter from Class III to Class II.

Class II Exemption Petitions

- Granted a Class II exemption on March 3, 2000, for vascular tunnelers submitted by Impra, Inc.

Final 515(b) Calls for PMAs

- Published a final rule in the *Federal Register* on April 12, 2000, Effective Date of Requirement for Premarket Approval of the penile inflatable implant.

- Published a final rule in the *Federal Register* on April 13, 2000, Effective Date of Requirement for Premarket Approval for three Preamendment Class III Devices (lung water monitor, powered vaginal muscle stimulator, and stair-climbing wheelchair).

- Published a final rule in the *Federal Register* on July 5, 2000, Effective Date of Requirement for Premarket Approval for a Class III Preamendments Obstetrical and Gynecological Device.

- Published a final rule in the *Federal Register* on September 26, 2000, Effective Date of Requirement for Premarket Approval of the Implanted Mechanical/Hydraulic Urinary Continence Device.

Part 4 – Program Support

Guidance for Industry and Reviewers

In FY 00, ODE published 25 final guidance documents and published 5 draft guidance documents for comment. See INDUSTRY INFORMATION for a complete listing of all ODE guidance documents published in FY 00.

Least Burdensome

The FDA Modernization Act of 1997 contains a charge to FDA to require only clinical data or information necessary to establish device effectiveness or to confer substantial equivalence. FDA must consider the least burdensome means of demonstrating effectiveness or equivalence in the review of premarket applications. Pursuant to this congressional mandate, ODE has taken the lead in implementing the concept of "least burdensome." As part of this effort, ODE actively participated in a CDRH-wide working group on least burdensome issues. As part of the efforts to implement the least burdensome provisions of FDAMA, ODE's internal tracking documents and correspondence with companies have been modified to highlight least burdensome efforts. Working collaboratively with an Industry Task Force, ODE participated in the preparation of a draft "Concepts and Principles" document. Efforts are continuing, both internally and with the Industry Task Force, to implement the least burdensome provisions in all of our activities. Information related to the least burdensome provisions of the FDA Modernization Act of 1997 can be accessed on the CDRH website: http://www.fda.gov/cdrh/modact/leastburdensome.html.

Significant Jurisdictional Issues Involving Devices in FY 2000

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 FDA Office of the Chief Mediator and Ombudsman. These formal submissions contain the material describing the requester's product and their proposal regarding which Center should be given the lead designation over the product and whose authorities (Biological, Device or Drug) should apply.

In FY 2000, CDRH participated in the review of 21 out of 23 RFDs (two were assigned wholly to CDER and CBER only) in addition to completing the review of 2 RFDs received in FY 99. The reviews of the 21 new requests were assigned to the ODE Divisions as follows; DGRND was assigned to review seven and shared an additional review with DOED, DDIGD and DCRD were assigned five each, DOED was assigned

one and shared one with DGRND, and DCLD was assigned one RFD. Finally, one was not assigned to any division as it was handled by the Center's coordinator for incoming RFDs.

Out of the 21 RFDs assigned to CDRH for review, seven were not due for completion until FY 2001. Of the 16 RFD's whose reviews were completed, CDRH was assigned the lead center in 10 of those requests and one was withdrawn before its review could be completed. Of the remaining five the lead center designation was to either CDER or CBER.

Advisory Panel Activities

The Center's Medical Devices Advisory Committee (MDAC) provides advice to FDA on the safety and effectiveness of marketed and investigational devices, the classification of devices into one of three regulatory categories, the possible risks to health associated with the use of devices, the formulation of product development protocols, the review of premarket approval applications, and the content of guidelines or guidance documents designed to improve the interaction between the Agency and sponsors of medical devices. The MDAC consists of 18 panels divided according to medical device specialties.

In FY 00, ODE held 27 panel meetings, 12 open meetings and 15 partially closed. Of the 18 panels, four met at least once, four met twice, and five met three times during the fiscal year. The panels collectively considered 28 PMA submissions, five PMA Supplements, four Reclassifications, two PDPs, one 510k, and two guidance documents. The panels discussed and provided advice on a number of issues. Topics ranged, for example, from the design of clinical trials to support claims for reduced posterior capsular opacification for intraocular lenses, devices used in atrial fibrillation therapies, to assessing the performance of *in vitro* diagnostic tests for hepatitis infection. Further information about government-wide advisory committees is available at the Federal Advisory Committee Act Database on the GSA website: http://204.254.112.5/cms.

There were 25 formal training sessions for new panel members (special government employees known as SGEs). The two-hour training for SGEs covered the laws and regulations with respect to medical devices, organizational structure of the Agency, ODE's operations, the roles and responsibilities of panel members, the elements of a panel meeting, and conflict of interest.

Panel members are leading authorities in a broad range of medical areas and have current experience in medical practice, teaching and/or research. Each panel has a consumer representative, an industry representative, and when appropriate, a patient representative; these panel members do not vote but provide valuable input into panel discussions. Patient

representatives served on two panels during the fiscal year – the Clinical Chemistry and Clinical Toxicology Devices Panel meeting on December 6 and 7, 1999, and the Neurological Devices Panel on March 31, 2000. During the past fiscal year, females made up 43% of the ODE panel membership and minorities approximately 31%.

ODE continuously recruits highly qualified experts to serve as consultants and panel members. 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 resume to the Advisory Panel Coordinator, Office of Device Evaluation, 9200 Corporate Boulevard, Rockville, Maryland 20850.

Announcements of panel meetings are publicized in several ways: voice information via the FDA Advisory Committee Information Line (1-800-741-8138), printed information in the Federal Register, and on the Internet (http://www.fda.gov/cdrh/panelmtg.html). This website also includes summaries of the most recent advisory panel meetings.

The Guidance on Amended Procedures for Advisory Panel Meetings was revised on July 22, 2000, to clarify the standard operating procedures that apply to advisory panel meetings where a specific submission is being considered by the panel or to device classification panel meetings on issues involving more than one sponsor. The clarification addresses timeframes for when and what types of information/new data analyses might be submitted to the panel. The revised guidance is available at http://www.fda.gov/cdrh/modact/amendpan.html.

ODE Integrity Program

During this fiscal year, ODE investigated about 62 cases concerning the integrity of data submitted to the agency in premarket applications. Under the Application Integrity Program (AIP), two firms were placed on the AIP list and AIP restrictions applied against these firms.

ODE handled 37 instances related to questions arising under the standards of conduct for employees. During FY 00, as in years past, the ODE 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/laws_regs_fedreg_stats/oge_regs/5cfr2635.html.

Freedom of Information Requests

ODE staff received 1,080 FOI requests during FY 00, a decrease from 1,355 last fiscal year. During FY 00, the number of FOI requests closed was 1,146 compared to 834 in

FY 99. The total number of FOI requests pending in ODE at the end of FY 00 is 621 compared to 771 in FY 99.

Congressional Inquiries

Congressional interest in ODE programs continued to be strong in FY 00. ODE staff responded to inquiries and participated in briefings on such topics as hearing aids, breast implants, drug test kits, dental amalgam/illness, hemodialysis, and reuse. ODE also participated in Congressional hearings held during FY 00 dealing with FDA's budget, FDAMA, reuse, and genetic testing.

Publications

During FY 00, ODE staff authored 20 manuscripts for publication in professional and scientific journals and delivered 58 presentations at professional, scientific and trade association meetings. See Appendix B for a bibliography of publications.

ODE Vendor Day

In FY 00, ODE, in conjunction with the regulatory industry, sponsored one Vendor Day - an informative exhibit and exchange seminar with device manufacturers on cardiovascular, general and restorative, clinical laboratory and other devices.

Site Visits

In FY 00, ODE continued its Site Visit Program that was developed 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 hospitals for the observation of certain devices in use. As a result, 11 firms and/or hospitals were visited to learn about orthopedic products, blood-glucose products, endovascular grafts, dialysis systems, IVD products, condoms, and other devices.

In-House Training

ODE employees attended many courses, lecturers, and grand rounds sponsored by the CDRH Staff College. Supervisors continued to participate in monthly meetings to discuss current management issues, and all employees attended all-hands meetings to learn about new FDAMA polices and procedures.

ODE sponsored three in-house training courses for employees and managers: Media Relations Workshop, Congressional Hearings Workshop and Interviewing Techniques.

Mentoring Program

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

Other Employee Programs

In FY 2000, ODE continued and expanded the ODE Intern Program. The program allows 4-5 college students to work in a practical work environment, gain entry level professional "real work" experience and work alongside some the Agency's top healthcare authorities. Special attention is given to minority candidates. ODE continues to expand the program to include American and foreign professionals.

ODE, along with a sister organization, the Office of Health Industry Programs, continued the DSMA/ODE Exchange Program, an internal program that allows scientific reviewers from each Office to exchange places for a period of 60-90 days. Each participant is expected to learn about the operations and integral workings of the other Office.

ODE established the ODE Employee Exchange Program. The primary purpose of the program is to allow staff members the opportunity to work in other Offices and Centers within FDA to keep abreast of current advances and practices in sister organizations, as well as changes in legislation, regulations, scientific and legislative literature in other medical fields.

Minority Recruitment

In an effort to increase the hiring of minorities within the Center, ODE participated in various recruitment and job fairs including the President's Committee on the Employment of People with Disabilities Job Fair and the Hispanic Association of Colleges and Universities (HACU) Employment Fair.

Computer Tracking Systems

ODE tracking system changes included premarket database enhancements, revised query programs and performance reports, and the development and implementation of

the CLIA categorization tracking system, the 510(k) Exempt CLIA submission tracking system, and the 513(g) (device determination) tracking system. In addition, revisions were made in the Classification database for the expanded third party review and to the PMA modular review tracking system. The ODE division tracking system was updated to accommodate CLIA and 513(g) submissions and to produce new reports. All tracking systems were modified to reflect the division reorganizations of ODE.

Office Automation

ODE continued to upgrade equipment in order to improve the processing of applications and interactions with the regulated industry and the public. Speakerphones, Windows NT on all PCs, laptops, PCs, laser printers, uninterruptible power supplies, and facsimile machines were among the improvements. In addition, ODE contributed funds to upgrade the Center's telephone system to enable dial-in access speeds to approach 56K and to help with the development of a new storage system for archived documents.

Electronic Submissions

In FY 00, ODE received 113 electronic submissions for PMAs, IDEs, and 510(k)s from 37 different sponsors. ODE reviewers received parts of submissions in electronic format such as additional information, summaries of safety and effectiveness, and proposed labeling and those submissions were recorded as electronic submissions. Prior contact with an ODE division is requested before developing and sending an electronic submission. Instructions for submitting electronic submissions can be found on the FDA home page at the address http://www.fda.gov/cdrh/elecsub.html.

Video Conferencing

The ODE use of videoconferencing to interact with the regulated industry continued to show limited use. In FY 00, 8 videoconferences were held involving industry, other Federal agencies and professional societies. 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.

World Wide Web Activity

ODE continues to provide information on the web that can be downloaded and searched through the CDRH home page at http://www.fda.gov/cdrh. Information on Premarket Approval Applications (PMAs) and Premarket Notifications (510(k)s) can be found under the Popular Items/New Device Information on the CDRH home page.

Anyone can search the Releasable 510(k) and PMA databases, download 510(k) or PMA files, obtain the monthly PMA, HDE and 510(k) listings and Summaries of Safety and Effectiveness Data, and read about the "Real-Time" program for PMA supplements. A database of guidance documents is available at the address http://www.fda.gov/cdrh/ggpmain.html. The database is searchable by words in the document title, office, division, or any combination of these elements. In FY00, ODE posted 39 guidance documents on the web. In addition, information on ODE's panel meeting schedules and summaries can be found on the internet at http://www.fda.gov/cdrh/panelmtg.html.

Device Databases

Center for Devices and Radiological Health (CDRH) maintains searchable databases of devices previously approved for marketing or declared substantially equivalent to a legally marketed device at http://www.fda.gov/cdrh/mda/mda-databases.html.

Consumer Information

The Consumer Staff in FDA's Center for Devices and Radiological Health, Division of Small Manufacturers Assistance also provides information to consumers regarding medical devices and radiation-emitting products to enhance their 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.shtml
E-Mail: dsma@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

The FDA Breast Implant website for consumer information is available at http://www.fda.gov/cdrh/breastimplants/index.html.

A new CDRH website entitled LASIK Eye Surgery: Learning About LASIK is available at http://www.fda.gov/cdrh/lasik/.

Part 5 – Operational Summary

[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. There are also likely to be changes in the previous years' annual report numbers in tables representing receipt cohort data. 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 96 - FY 00

Type of Submission	Number Received				
	FY 96	FY 97	FY 98	FY 99	FY 00
Premarket Approval (PMAs)					
Original Applications	44	66	47	60	67
Amendments	883	829	710	767	978
Supplements	415	409	513	552	545
Amendments to Supplements	823	819	863	924	932
Reports for Orig. Applications	435	435	431	406	419
Reports for Supplements	24	2	0	0	0
Master Files	65	130	94	25	44
PMA Subtotal	2,689	2,690	2,658	2,734	2,985
Humanitarian Device Exemptions (HDEs)					
Original Applications	0	4	8	12	11
Amendments	0	10	32	55	56
Supplements	0	0	0	4	10
Amendments to Supplements	0	0	0	3	12
Reports for Orig. Applications	0	0	0	6	9
Reports for Supplements	0	0	0	0	0
HDE Subtotal	0	14	40	80	98
Investigational Device Exemptions (IDEs)					
Original Applications	253	297	322	304	311
Amendments	219	223	226	275	240
Supplements	3,189	3,776	4,277	4,127	4,388
IDE Subtotal	3,661	4,296	4,825	4,706	4,939
Premarket Notification (510(k)s)					
Original Notifications	5,297	5,049	4,623	4,458	4,202
Supplements	3,246	2,785	2,023	1,872	1,742
Amendments	5,343	4,433	3,692	2,962	2,953
510(k) Subtotal	13,886	12,267	10,338	9,292	8,897
PMA/HDE/IDE/510(k) Total	**20,236**	**19,267**	**17,861**	**16,812**	**16,919**

Table 4. Original PMA Decision Cohort Performance*
FY 96 - FY 00

	FY 96	FY 97	FY 98	FY 99	FY 00
Number Received	44	70	55	72	67
PMA Actions					
Filing Decisions					
Filed	45	58	51	65	64
Not Filed	17	16	10	7	4
Others	0	0	0	0	0
Filing Decision Subtotal	62	74	61	72	68
Scientific Review Decisions					
Major Deficiencies	32	38	28	32	51
Minor Deficiencies	5	5	10	4	11
Other[a]	97	138	105	105	111
Scientific Review Decisions Subtotal	134	181	143	141	173
Approval Decisions					
Approvals	43	48	46	45	43
Approvable	27	14	7	7	33
Not Approvable	6	5	12	1	4
Denials	0	0	0	0	0
Approval Decision Subtotal	76	67	65	53	80
Total PMA Actions	272	322	269	266	321
Average Review Time (Days)					
for Approvals[b]					
FDA	289	207	154	149	158
Non-FDA	55	40	37	26	40
Total	343	247	191	175	198
Average Elapsed Time (Days)					
for Approvals[c]					
FDA	572	375	265	280	244
Non-FDA	214	122	108	100	119
Total	786	497	373	380	363
Number under Review at End of Period[d]					
Active[e]	57	44	29	49	35
(Active and overdue)	(17)	(0)	(0)	(0)	(0)
On hold[f]	39	41	41	38	41
Total	96	85	70	87	76

*/ For FY 97, 98 and 99, PMA data includes a special category of PMAs. Humanitarian Devices Exemption (HDE) applications are similar in both form and content to PMAs but are exempt from the effectiveness requirements of PMAs. An approved HDE authorizes marketing of the humanitarian use device.

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 the 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. Number of months based upon 30.4 day/month and rounded to one decimal point.

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 96 – FY 00

	FY 96	FY 97	FY 98	FY 99	FY 00
Original PMAs Received					
PMAs	37	46	32	48	42
Expedited PMAs	5	10	6	7	4
Total	42	56	38	55	46
Filing Decisions[a]					
Filed	42	56	38	55	46
Not Filed	11	8	3	1	2
Number (%) of Filing/Not Filing Decisions within 45 Days	26(49)	51(80)	30(73)	44(79)	39(81)
Average Days/Cycle	67	39	44	42	40
Final Actions[b]					
Approvals	28	45	26	38	12
Denials	0	0	0	0	0
Other[c]	18	22	15	9	8
Total	46	67	41	47	20
Filing to First Action Excluding withdrawals, conversions, etc.[d]					
Number Received and Filed	42	56	38	55	46
Number of First Actions	37	53	37	55	41
Average FDA Days	195	147	134	145	139
Median FDA Days	187	175	145	147	160
Number (%) of First Actions within 180 Days	18(43)	41(73)	32(84)	43(78)	41(89)
Filing to First Action Including withdrawals, conversions, etc.[e]					
Number Received and Filed	42	56	38	55	46
Number of First Actions	42	56	38	55	46
Average FDA Days	228	146	134	145	140
Median FDA Days	183	173	141	147	152
Number (%) of First Actions within 180 Days	20(48)	43(77)	33(87)	43(78)	46(100)
Filing to Final Actions Excluding withdrawals, conversions, etc.[f]					
Number Received and Filed	42	56	38	55	46
Number of Final Actions	30	45	28	35	15
Average FDA (Total) Elapsed Time	358(514)	264(346)	239(321)	244(293)	164(214)
Median FDA (Total) Elapsed Time	329(408)	217(287)	198(201)	240(269)	178(211)
Number (%) of Final Actions within 180 FDA Days	6(20)	19(42)	12(43)	7(20)	11(73)
Number (%) of Final Actions within 180 Total Days	4(13)	16(36)	10(36)	5(14)	5(33)
Filing to Final Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	42	56	38	55	46
Number of Final Actions	42	54	34	38	23
Average FDA (Total) Elapsed Time	378(530)	257(373)	224(355)	245(303)	161(200)
Median FDA (Total) Elapsed Time	321(420)	200(315)	187(252)	243(271)	175(195)
Number (%) of Final Actions within 180 FDA Days	8(19)	23(43)	17(50)	8(21)	18(78)
Number (%) of Final Actions within 180 Total Days	6(14)	18(33)	11(32)	5(13)	10(44)
Average Number of FDA Cycles from Receipt to Final Action Including Withdrawals, conversions, etc [b].	1.9	1.7	1.7	1.8	1.3

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Table 5. Original PMA Receipt Cohort Performance*
FY 96 – FY 00

(Continued from previous page.)

	FY 96	FY 97	FY 98	FY 99	FY 00
Percentile FDA Days from Filing to First Action[e]					
25th	165	111	99	115	113
50th (Median)	183	173	141	147	152
75th	231	180	174	179	176
90th	316	199	181	227	179
Percentile FDA Days from Filing to First Action[d]					
25th	171	118	99	115	116
50th (Median)	187	175	145	147	160
75th	252	182	175	179	179
90th	--	217	192	227	--
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	233(272)	165(177)	141(158)	185(236)	120(175)
50th (Median)	321(420)	200(315)	187(252)	243(271)	175(195)
75th	432(785)	382(520)	289(564)	284(384)	181(234)
90th	712(961)	440(708)	392(789)	341(481)	202(280)
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	233(272)	170(177)	157(158)	185(234)	147(178)
50th (Median)	329(408)	217(287)	198(201)	240(269)	178(211)
75th	419(779)	390(520)	328(387)	284(372)	181(240)
90th	710(987)	440(680)	392(801)	341(437)	228(280)
Number pending as of 9/30/00					
Active	0	1	0	8	8
Active and Overdue	0	0	0	0	0
On hold[h]	0	1	7	9	16
Total	0	2	7	17	24
Summary of PMA Receipt Cohort					
Approved	28	45	26	38	12
Denied	0	0	0	0	0
Withdrawn	11	11	9	3	6
Other	7	11	6	6	2
Under Review	0	1	0	8	8
On Hold[h]	0	1	7	9	16
Total	46	69	48	64	44

*/ For each fiscal year, September 30, 2000 was used as the cutoff date. The FY 00 cohort represents only receipts through March 31, 2000 (first six 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.

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 agency 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.

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Table 5. Original PMA Receipt Cohort Performance FY 96 – FY 00

(Continued from previous page.)

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 actions 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 96 - FY 00

	FY 96	FY 97	FY 98	FY 99	FY 00
Number Received	415	409	513	556	545
PMA Supplement Actions					
Panel Track Filing Decisions[a]					
Filed	8	15	7	17	14
Not Filed	1	1	2	2	3
Other	0	0	0	0	0
Filing Decision Subtotal	9	16	9	19	17
Scientific Review Decisions					
Major Deficiencies	9	3	4	12	14
Minor Deficiencies	1	1	2	0	1
Other[b]	141	128	62	60	83
Scientific Review Decisions Subtotal	151	132	68	72	98
Approval Decisions					
Panel track approvals[c]	0	4	5	11	12
Nonpanel track approvals	462	397	416	426	462
Approvable	33	49	47	25	100
Not approvable	48	76	63	62	58
Approval Decision Subtotal	543	526	531	524	632
Total PMA Supplement Actions	703	674	608	615	747
Average Review Time (Days) for Approvals[d]					
FDA	146	100	82	76	76
Non-FDA	36	12	25	16	18
Total	182	112	107	92	94
Average Elapsed Time (Days) for Approvals[e]					
FDA	167	120	109	92	95
Non-FDA	49	23	43	26	27
Total	216	143	153	118	122
Number under Review at End of Period[f]					
Active[g]	162	110	139	158	98
(Active and overdue)	(17)	(0)	(0)	(0)	(0)
On hold[h]	74	80	57	70	84
Total	236	190	196	228	182

*/ For FY 97, 98 and 99, PMA data includes a special category of PMAs. Humanitarian Devices Exemption (HDE) applications are similar in both form and content to PMAs but are exempt from the effectiveness requirements of PMAs. An approved HDE authorizes marketing of the humanitarian use device.

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 of the supplement, the status of the supplement as a special (changes being effected) or 30-day submission, and other miscellaneous administrative actions.

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. Number of months based upon 30.4 day/month and rounded to one decimal point.

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, 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.

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's processing of application officially suspended pending receipt of additional information from the applicant.

Table 7. PMA Supplement Receipt Cohort Performance*
FY 96 - FY 00

	FY 96	FY 97	FY 98	FY 99	FY 00
PMA Supplements Received					
PMA Supplements	410	402	510	541	270
Expedited PMA Supplements	3	3	1	6	1
Total	413	405	511	547	271
Filing Decisions[a]					
Filed	4	6	9	15	7
Not Filed	0	1	1	0	1
Number of Filing/Not Filing Decisions within 45 Days	3	5	9	10	7
Average Days/Cycle	45	45	42	45	43
PMA Supplement Final Actions[b]					
Approvals	379	369	427	441	200
Denials	0	0	0	0	0
Other[c]	34	36	82	84	47
Filing to First Action Excluding withdrawals, conversions, etc.[d]					
Number Received and Filed	413	405	511	547	271
Number of First Actions	398	396	491	526	265
Average	122	90	82	74	67
Median	130	73	59	39	42
Number (%) of First Actions within 180 Days	311(75)	350(86)	433(87)	475(87)	262(97)
Filing to First Action Including withdrawals, conversions, etc.[e]					
Number Received and Filed	413	405	511	547	271
Number of First Actions	411	405	509	544	271
Average	121	91	80	74	67
Median	126	70	49	37	39
Number (%) of First Actions within 180 Days	322(78)	357(88)	460(90)	491(90)	268(99)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[b]	1.2	1.1	1.1	1.1	1.0
Filing to Final Action Excluding withdrawals, conversions, etc.[f]					
Number Received and Filed	413	405	511	547	271
Number of Final Actions	379	367	460	486	240
Average FDA (Total) Review Days	148(185)	106(129)	94(118)	79(95)	66(76)
Median FDA (Total) Review Days	132(150)	70(83)	49(66)	35(47)	35(43)
Number (%) of Final Actions Within 180 Days	259(68)	304(83)	374(81)	420(86)	234(98)
Number (%) of Final Actions Within 180 Total Days	236(62)	286(78)	352(77)	406(84)	225(94)
Filing to Final Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	413	405	511	547	271
Number of Final Actions	413	400	503	517	247
Average FDA (Total) Review Days	147(202)	110(147)	97(131)	82(102)	66(75)
Median FDA (Total) Review Days	132(156)	74(94)	51(69)	36(50)	35(43)
Number (%) of Final Actions Within 180 Days	284(69)	324(81)	490(97)	447(87)	241(98)
Number (%) of Final Actions Within 180 Total Days	249(60)	296(74)	371(74)	424(82)	232(94)

(Continued on next page.)

Table 7. PMA Supplement Receipt Cohort Performance*
FY 96 - FY 00

(Continued from previous page.)

	FY 96	FY 97	FY 98	FY 99	FY 00
Percentile FDA Days from Filing to First Action[e]					
25th	57	29	22	19	20
50th (Median)	126	70	49	37	39
75th	179	155	156	140	113
90th	196	181	180	181	165
Percentile FDA Days from Filing to First Action[d]					
25th	63	32	22	20	21
50th (Median)	130	73	59	39	42
75th	180	165	169	151	116
90th	201	182	183	190	170
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	63(76)	33(36)	22(24)	20(24)	18(24)
50th (Median)	132(156)	74(94)	51(69)	36(50)	35(43)
75th	187(225)	169(182)	175(182)	147(161)	109(118)
90th	296(446)	216(351)	212(322)	190(232)	165(172)
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	64(76)	32(35)	22(25)	19(24)	18(24)
50th (Median)	132(150)	70(83)	49(66)	35(47)	35(43)
75th	187(210)	162(179)	175(179)	141(152)	108(117)
90th	303(379)	207(313)	213(281)	190(214)	165(174)
Number under review as of 9/30/00					
Active	0	0	0	5	4
Active and Overdue	0	0	0	2	0
On hold[h]	0	5	8	25	20
Total	0	5	8	32	24
Summary of PMA Supplement Receipt Cohort					
Approved	379	369	427	441	200
Denied	0	0	0	0	0
Withdrawn	28	28	30	32	6
Other	6	8	52	52	41
Under Review	0	0	0	7	4
On Hold[h]	0	5	8	25	20
Total	413	410	517	557	271

*/ For each fiscal year, September 30, 2000 was used as the cutoff date. The FY 00 cohort represents only receipts through March 31, 2000 (first six 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 as 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.

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 actions 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.

(Continued on next page.)

Table 7. PMA Supplement Receipt Cohort Performance*
FY 96 - FY 00

(Continued from previous page.)

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. HDE Submissions Received
FY97 – FY00

Type of Submission	Number Received			
	FY 97	FY 98	FY 99	FY 00
Humanitarian Device Exemption (HDE)				
Original Applications	4	8	12	11
Amendments	10	32	55	56
Supplements	0	0	4	10
Amendments to Supplements	0	0	3	12
Reports for Orig. Applications	0	0	6	9
Reports for Supplements	0	0	0	0
HDE Subtotal	14	40	80	98

Table 9. Original HDE Decision Cohort Performance

FY97 – FY00

	FY 97	FY 98	FY 99	FY 00
Number Received	4	8	12	11
HDE Actions				
Filing Decisions				
Filed	2	9	10	8
Not Filed	0	1	1	4
Other[a]	0	1	1	0
Filing Decision Subtotal	2	11	12	12
Scientific Review Decisions				
Major Deficiencies	0	0	6	7
Minor Deficiencies	1	1	0	3
Other[b]	0	0	4	6
Scientific Review Decisions Subtotal	1	1	10	16
Approval Decisions				
Approvals	2	4	6	6
Approvable	0	0	5	1
Not Approvable	0	0	0	0
Denials	0	0	0	0
Approval Decision Subtotal	2	4	11	7
Other Final Decisions[c]	0	2	4	1
Total HDE Actions	5	18	37	36
Filing to First Action[d]				
Number of First Actions	2	6	13	8
Average Number of FDA Days	68	139	87	61
Number of First Actions Within 75 Days	1	1	7	8
Average Elapsed Time (Days) for Approvals[e]				
FDA	108	152	113	112
Non-FDA	12	0	50	104
Total	120	152	163	216
Average Number of FDA Cycles from Receipt to Final Action[f]	1	1.2	1.2	1.3
Number under Review at End of Period				
Active	2	3	2	2
Active and overdue	0	0	0	0
On hold	0	1	8	8
Total	2	4	10	10

a/ Includes 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 or conversion to another regulatory category.
d/ 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.
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 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.
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 10. HDE Supplement Decision Cohort Performance FY97 – FY00

	FY 97	FY 98	FY 99	FY 00
Number Received	0	0	4	10
HDE Supplement Actions				
Scientific Review Decisions				
Major Deficiencies	0	0	1	0
Minor Deficiencies	0	0	0	0
Other[a]	0	0	2	0
Scientific Review Decisions Subtotal	0	0	3	0
Approval Decisions				
Approvals	0	0	3	10
Approvable	0	0	1	0
Not Approvable	0	0	0	1
Denials	0	0	0	0
Approval Decision Subtotal	0	0	4	11
Other Final Decisions[b]	0	0	0	0
Total HDE Actions	0	0	7	11
Filing to First Action[c]				
Number of First Actions	0	0	4	10
Average Number of FDA Days	0	0	57	44
Number of First Actions Within 75 Days	0	0	4	10
Average Elapsed Time (Days) for Approvals[d]				
FDA	0	0	70	43
Non-FDA	0	0	24	33
Total	0	0	94	76
Average Number of FDA Cycles from Receipt to Final Action[e]	0	0	1.3	1.0
Number under Review at End of Period[f]				
Active[g]	0	0	0	0
Active and overdue	0	0	0	0
On hold[h]	0	0	1	1
Total	0	0	1	1

a/ Includes actions that did not result in a final decision, such as GMP deficiency letter or an applicant-directed hold.
b/ Includes final actions other than approval or denial, such as withdrawal or conversion to another regulatory category.
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 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 11. Original IDEs
FY 96 - FY 00

	FY 96	FY 97	FY 98	FY 99	FY 00
Number Received	253	297	322	304	311
Number of Decisions					
Approved	171	172	201	176	213
Not approved	63	79	82	82	66
Other[a]	26	21	42	47	41
Total	260	272	325	305	320
Percent (%) of Approvals Made during First Review Cycle[b]	73	69	71	68	76
Average FDA Review Time (days)	28	29	27	27	28
Percent (%) of Decisions Made within 30 Days	99[d]	100	100	99	99
Number under Review at End of Period[c]	8	32	29	28	19
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 less approvals) because of deletions and conversions which are not reflected in the table.

d/ In October 1995, ODE moved its offices from Piccard Drive to Corporate Boulevard in Rockville, Maryland. ODE accepted premarketing submissions during the 14-day moving period but added 2 weeks to the due dates of IDEs. This 2-week delay is reflected in the percent of decisions made within the 30 days for original IDEs and amendments. This policy was announced in two notices in the *Federal Register* of October 14, 1994 (pg. 52170) and November 29, 1994 (pg. 60092).

Table 12. IDE Amendments
FY 96 - FY 00

	FY 96	FY 97	FY 98	FY 99	FY 00
Amendments Received[a]	219	223	226	275	240
Decisions on Amendments					
Approved	98	101	94	97	107
Not approved	29	25	36	42	34
Other[b]	91	94	95	129	110
Total	218	220	225	268	251
Average FDA Review Time (days)	18	18	19	18	19
Percent (%) of Decisions Made within 30 Days	98[e]	100	100	100	100
Average Approval Time (days) for IDEs with Amendments					
FDA time	53	61	55	57	70
Non-FDA time	78	84	35	88	66
Total time[c]	131	145	90	145	136
Number of Amendments per Approved IDE	1.4	1.8	1.4	1.6	2.3
Amendments under Review at End of Period[d]	9	12	13	19	9
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.

e/ In October 1995, ODE moved its offices from Piccard Drive to Corporate Boulevard in Rockville, Maryland. ODE accepted premarket submissions during the 14-day moving period but added 2 weeks to the due dates of IDEs. This 2-week delay is reflected in the percent of decisions made within the 30 days for original IDEs and amendments. This policy was announced in two notices in the *Federal Register* of October 14, 1994 (pg. 52170) and November 29, 1994 (pg. 60092).

Table 13. IDE Supplements
FY 96 - FY 00

	FY 96	FY 97	FY 98	FY 99	FY 00
Number Received	3,189	3,776	4,277	4,127	4,388
Number of Decisions	3,121	3,777	4,209	4,224	4,335
Average FDA Review Time (days)	21	21	21	20	20
Percent (%) of Decisions Made within 30 Days	99	100	100	100	100
Number under Review at End of Period[a]	148	216	284	187	239
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 14. 510(k) Decision Cohort Performance
FY 96 - FY 00

	FY 96	FY 97	FY 98	FY 99	FY 00
Number Originals Received	5,297	5,049	4,623	4,458	4,202
Number of Decisions					
Substantially equivalent	4,501	4,405	3,824	3,652	3,567
Not substantially equivalent	64	57	65	66	52
Other[a]	998	693	1,340	875	778
Total	5,563	5,155	5,229	4,593	4,397
Percent(%) not substantially Equivalent[b]	1.4	1.3	1.7	1.8	1.4
Average Review Time (days)					
FDA time[c]	110	97	89	80	77
Total time[d]	145	130	114	102	102
Median Review Time (days)					
FDA time[c]	85	81	81	71	68
Total time[d]	88	85	83	76	72
Percent (%) of Decisions made within 90 Days, based on					
FDA time[e]	80	95	97	99	100
Total time[d]	50	58	59	66	66
Number under Review at End of Period[f]					
Active[g]	1,408	1,287	1,057	943	850
(Active and overdue)	0	0	0	0	0
On hold[h]	821	865	487	461	370
Total	2,229	2,152	1,544	1,404	1,220

a/ 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.

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 additional 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 15. 510(k) Receipt Cohort Performance*
FY 96 - FY 00

	FY 96	FY 97	FY 98	FY 99	FY 00
Number of 510(k)s Received[a]					
Traditional	5,318	5,059	4,528	3,985	2,598
Special	0	0	80	396	456
Abbreviated	0	0	21	85	104
Total Receipts	5,318	5,059	4,629	4,466	3,158
Actions on 510(k)s					
Substantially Equivalent	4302	4150	3569	3579	2,333
Not Substantially Equivalent (%)[b]	57(1.3)	53(1.3)	68(1.9)	60(1.7)	24(1.0)
Other[c]	959	856	984	777	399
Total Actions	5,318	5,059	4,621	4,416	2,756
Average Cumulative Days for 510(k) Decisions Excludes Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	93	91	82	79	61
Total Time from Receipt to Final Decision[e]	120	116	103	100	73
All Decisions Including Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	91	89	81	78	60
Total Time from Receipt to Final Decision[e]	150	134	116	109	75
Number of Decisions (%) within 90 Days, Based on:					
FDA Days from Receipt to First Action	4,998(94)	4,968(98)	4,612(100)	4,454(100)	3,150(100)
FDA Cumulative Days from Receipt to Final Decision	3,472(65)	3,558(70)	3,530(76)	3,367(75)	2,452(78)
Total Cumulative Days from Receipt to Final Decision[e]	2,901(55)	3,025(60)	3,025(65)	2,938(66)	2,214(70)
Average Number of FDA Cycles from Receipt to Final Action	1.5	1.5	1.4	1.4	1.3
Percentile FDA (Total) Days from Receipt to Final Action					
25th	51(59)	51(57)	47(51)	41(45)	34(41)
50th (Median)	80(88)	80(86)	75(83)	71(78)	64(71)
75th	115(188)	106(175)	90(149)	90(147)	90(123)
90th	173(332)	172(312)	160(256)	162(265)	N/A(N/A)
Number under review as of 9/30/00					
Active	0	0	0	16	168
Active and Overdue	0	0	0	0	0
On hold	0	0	8	34	234
Total	0	0	8	50	402
Summary of 510(k) Receipt Cohort					
Substantially Equivalent	4,302	4,150	3,569	3,579	2,333
Not Substantially Equivalent	57	53	68	60	24
Other	959	836	984	777	399
Under Review	0	0	0	16	168
On Hold	0	0	8	34	234
Total	5,318	5,059	4,629	4,466	3,158

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Table 15. 510(k) Receipt Cohort Performance*
FY 96 - FY 00

(Continued from previous page.)

*/ For each fiscal year, September 30, 2000 was used as the cutoff date. The FY00 cohort represents only receipts through June 30, 2000 (first nine months of the fiscal year).

a/ IncludesThird Party 510(k)s: FY97 = 14; FY98 = 18; FY99 = 32; FY00 = 30.

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 Programs

ODE is responsible for the program areas through which medical devices are evaluated and cleared for clinical trials and marketing. This Appendix provides summary information about the major programs administered by ODE 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), have 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 statue 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 2000.

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Staff College Presenters and Faculty

Aziz, Kaiser
Beers, Everette
Brown, Daniel W.C.
Durfor, Charles
Gantt, A. Doyle
Goode, Jennifer
Gutman, Steve
Horbowyj, Roxolana
Kammula, Raja
Kennell, Lisa
Lacy, Frank
Less, Joanne
Melvin, Marsha
Mishra, Nirmal
Morris, Janine
Neuland, Carolyn
Nutter, Cathy
Nguyen, Trinh
Phillips, Robert
Phillips, Philip
Poneleit, Kathy
Portnoy, Stuart
Rechen, Eric
Romanell, Lawrence
Rosecrans, Heather
Shulman, Marjorie
Sliva, Clara
Tillman, Donna-Bea
Turtil, Steven
Ulatowski, Tim
Weitershausen, Joanna
Witten, Celia
Zuckerman, Bram

Appendix C – 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 Assistance	http://www.fda.gov/cdrh/consumer/index.shtml
Federal Advisory Committee Act Database	http://204.254.1125/cms
FDA's Home Page	http://www.fda.gov
Guidance Documents	http://www.fda.gov/cdrh/ggpmain.html
Guidance Documents and PMA Approval Website	http://www.fda.gov/cdrh/mda/index.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 of the FDA Modernization Act of 1997	http://www.fda.gov/cdrh/modact/leastburdensome.html
Panel Meeting Schedules and Summaries	http://www.fda.gov/cdrh/panelmtg.html
Previously Approved/Cleared Devices	http://www.fda.gov/cdrh/mda/mda-databases.html
Recruitment Brochure	http://www.fda.gov/cdrh/ode/advbrochure01.html
Standards of Ethical Conduct	http://www.usoge.gov/pages/laws_regs_fedreg_stats/oge_regs/5cfr2635.html
Third Party	http:/www.fda.gov/cdrh/thirdparty

Appendix D – ODE Organization Chart

as of 1/8/01

OFFICE OF THE DIRECTOR

Director: Bernard Statland, M.D., Ph.D.
Deputy Director, Science & Regulatory Policy: Philip Phillips
Deputy Director, Clinical & Review Policy: Kimber Richter, M.D.
Deputy Director, Clinical & Review Policy: Daniel Schultz, M.D.
Integrity Officer: Carl DeMarco, J.D.

PROGRAM OPERATIONS STAFF (POS)

Director: Robert Gatling
PMA Section: Thinh Nguyen*
IDE Section: Joanne Less, Ph.D.
510(K) Section: Heather Rosecrans
Panel Coordinator: Sharon Lappalainen*

PROGRAM MANAGEMENT OFFICE (PMO)

Director: Kathryn Appler
Management Services Section: Lesa Dowtin
Office Automation Systems
& Support Section: Jeffrey Jaeger

DIVISION OF CARDIOVASCULAR AND RESPIRATORY DEVICES (DCRD)

Director: James Dillard
Deputy Director I: Stuart Portnoy, M.D.*
Deputy Director Ii: Stephen Rhodes*
Associate Director, Guidance & Policy: Arthur Ciarkowski
Clinical Trials Coordinator: Wolf Sapirstein, M.D.
Pacing, Defibrillator, And Leads Branch: Russell Pagano, Ph.D.
Cardiac Electrophysiology And Monitoring Devices Branch: Donna-Bea Tillman, Ph.D.
Anesthesiology And Respiratory Devices Branch: Joanna Weitershausen
Interventional Cardiology Devices Branch: Christopher Sloan
Circulatory Support & Prosthetic Devices Branch: Bette Lemperle
Peripheral Vascular Devices Branch: Vacant

DIVISION OF REPRODUCTIVE, ABDOMINAL, AND RADIOLOGICAL DEVICES (DRARD)

Director: Daniel Schultz, M.D.*
Deputy Director: David Segerson
Obstetrics/Gynecology Devices Branch: Colin Pollard
Urology & Lithotripsy Devices Branch: Janine Morris*
Gastroenterology & Renal Devices Branch: Carolyn Neuland, Ph.D.
Radiological Devices Branch: Robert Phillips, Ph.D.

DIVISION OF DENTAL, INFECTION CONTROL, AND GENERAL HOSPITAL DEVICES (DDIGD)

Director: Timothy Ulatowski
Infection Control Devices Branch: Chiu Lin, Ph.D.
Dental Devices Branch: Susan Runner, D.D.S.
General Hospital Devices Branch: Patricia Cricenti

DIVISION OF GENERAL, RESTORATIVE, AND NEUROLOGICAL DEVICES (DGRND)

Director: Celia Witten, M.D.
Deputy Director I: Mark Melkerson
Deputy Director Ii: Miriam Provost*
Plastic & Reconstructive Surgery Devices Branch: Pamela Scott*
General Surgery Devices Branch: Neil Ogden
Orthopedic Devices Branch: Barbara Zimmerman
Restorative Devices Branch: Diane Mitchell*

DIVISION OF CLINICAL LABORATORY DEVICES (DCLD)

Director: Steven Gutman, M.D.
Deputy Director : Donald St. Pierre
Associate Director, Special Programs: Joseph Hackett, Ph.D.
Associate Director, 510(K) & Outreach Program: Kaiser Aziz, Ph.D.
Chemistry And Toxicology Devices Branch I: Jean Cooper, Ph.D.
Chemistry And Toxicology Devices Branch Ii: Vacant
Immunology And Molecular Diagnostics Devices Branch: Peter Maxim, Ph.D.
Hematology And Cytology Devices Branch: Vacant
Virology Devices Branch: Woody Dubois, Ph.D.
Bacteriology Devices Branch: Vacant

DIVISION OF OPHTHALMIC AND EAR, NOSE, AND THROAT DEVICES (DOED)

Director: A. Ralph Rosenthal, M.D.
Deputy Director: Nancy C. Brogdon
Associate Director: David Whipple
Vitreoretinal & Extraocular Devices Branch: James Saviola, O.D.
Diagnostic & Surgical Devices Branch: Everette Beers*
Intraocular & Corneal Implants Branch: Donna Lochner
Ear, Nose, & Throat Devices Branch: James Saviola*

*Acting

Appendix E - ODE Staff Roster

Office of the Director

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Cooper, Brooksie
DeMarco, Carl
Gibbs, Danielle
Gornick, MaryAnn
Hobbs, Cathy
Phillips, Philip
Pluhowski, Nancy
Poneleit, Kathy
Richter, Kimber
Sauberman, Harry
Schultz, Dan
Statland, Bernard

Program Management Office

Appler, Kathryn
Broughton, Shirley
Cancino, Isella
Clingerman, Angie
Dowtin, Lesa
Dumas, Evalee
Howell, Kimberly
Jaeger, Jeff
Koviack, Bob
Robins, Lisa
Schielke, Mary
Wedlock, Chuck
Wilson, Robin

Program Operations Staff

Berk, Gene
Fisher, Lisa
Gatling, Robert
Less, Joanne
Lyons, Linda
Melvin, Marsha
Nguyen, Thinh
Parker, Mervin
Perticone, Diane
Rechen, Eric
Rosecrans, Heather
Sawyer-Major, Wanda
Shulman, Marjorie
Williams, Paul
Wolanski, Nicole

Division of Clinical Laboratory Devices

Aziz, Kaiser
Bautista, Josephine
Benson, Carol
Bernhardt, Pat
Blagmon, Djuana
Brindza, Larry
Bucher, Betty
Callaghan, Jim
Calvin, Veronica
Chace, Nina
Chan, Maria
Chenault, Michelle
Chesler, Ruth
Clark-Stuart, Michelle
Cooper, Jean
Dada, Valerie
Danishefsky, Avis
Diggs, Denise
Dubois, Woody
Fourcroy, Jean
Fugate, Kearby
Gaffey, Claudia
Gonzalez, Augustin
Gutierrez, Alberto
Gutman, Steve
Hackett, Joe
Hanna, Nancy
Hawthorne, Ann
Heyliger, Marian
Hyde, John

Ingram, Kenneth
Jones, Doris
King, Lisa
Lyle, Dave
MacArthy, Philip
Magruder, Louise
Maxim, Peter
McClain-Bennett, Joan
Michaud, Ginette
Moore, Deborah
Moxey-Mims, Marva
Peacock, Albert
Pinkos, Arleen
Poole, Freddie
Radha, Edappallath
Rao, Prasad
Reeves, Pat
Robinowitz, Max
Rogers, Liz
Selepak, Sally
Shively, Roxanne
Simms, Tom
Sliva, Clara
St. Pierre, Don
Summers, Peter
Ticehurst, John
Tsai, Miin-Rong
Vadlamudi, Kris
Weeks, Susan
Wei, Tena
Whitaker, Kathleen
Wilbon, Tonya
Wood, Geretta
Wright, Kathy

Division of Cardiovascular and Respiratory Devices

Abel, Dorothy
Bazaral, Mike
Berman, Mike
Brown, Michele
Buckley, Donna
Callahan, Tom
Carey, Carole
Chandeysson, Paul
Cheng, Jim
Ciarkowski, Art
Danielson, Judy
Demian, Cindy
Dillard, Jim
Donelson, Jan
Fleischer, Dina
Foreman, Christy
Foster, Elaine
Foy, Joni
Gabriel, Lynette
Gantt, Doyle
Gibbons, Gwen
Gomez-Novoa, Carmelina
Goode, Jennifer
Ho, Charles
Hottenstein, Omar
Huynh, Ann
Hwang, Shang
Jensen, Nick
Jones, Edwena
Kaiser, Suzanne
Karanian, John
Kennell, Lisa
Kroen, Marian
Kurtzman, Steve
Lacy, Frank
Lacy, Fred
Lee, James
Lemperle, Bette
Letzing, Bill
Lyle, Judy
Mazzaferro, Bob
Moynahan, Megan
Nakayama, Von
Nell, Diane
Noe, William
Oktay, Semih
O'Neill, Carroll
Parkhurst, John
Peters, Kimberly
Portnoy, Stuart
Puglisi, Mike
Roy, Joydeb

Ryan, Tara
Sapirstein, Wolf
Shanker, Rhona
Shein, Mitch
Sloan, Chris
Smallwood, Senora
Stuhlmuller, John
Subramanian, Ramiah
Terry, Doris
Tillman, Donna-Bea
Usher, Will
Wang, Emil
Weitershausen, Joanna
Wentz, Catherine
Zimmerman, Barbara
Zuckerman, Bram

Division of Dental, Infection Control, and General Hospital Devices

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Barrett, Sue
Betz, Robert
Bexabeh, Shewit
Blackwell, Angela
Blount, Sharon
Bolden, Brenda
Browne, Myra
Burdick, William
Cricenti, Pat
Cunningham, Terrell
Dorsey, Regina
Floyd, Chirelle
Foster, Sarah
Fox, Pat
Fuller, Janie
Hibbard, Viola
Hoard, Renita
Levchuck, John
Lin, Chiu
Marshall, Felicidad
Mayhall, Elaine
Naveau, Irene
O'Connell, Linh
O'Lone, Martha
Robinson, Mary Jo
Runner, Susan
Samuels-Reid, Joy
Scott, Pam
Shipps, Gerald
Shire, Sandra
Smith, Gwen
Soprey, Pandu
Trinh, Hung
Turtil, Steve
Ulatowski, Tim

Division of General, Restorative, and Neurological Devices

Allen, Peter
Allen, Samie
Anderson, Jodi
Arepalli, Sam
Basu, Sankar
Berkowitz, David
Bernato, Delores
Berne, Bernard
Biddle, Timothy
Blair, Therian
Bourke, Tracey
Bowsher, Kristen
Costello, Ann
Courtney, Mike
Dawisha, Sahar
DeLuca, Bob
Demian, Hany
Durfor, Charles
Einberg, Elmar
Eudy, Mike
Felten, Richard
Fogarty, Pauline
Foy, Keith
Gadaleta, Sergio
Gantt, Gail
Goode, John
Hammond, Della
Hinckley, Steve

Horbowyj, Roxi
Hudson, Peter
Kaiser, Aric
Keith, Erin
Kim, Sam
Krause, David
Lee, Kevin
Mattamal, George
Mattera, Michelle
Melkerson, Mark
Mishra, Nirmal
Morris, Janine
Ogden, Neil
Pagano, Russell
Pak, Yung
Phillips, Mary Ellen
Rhodes, Holly
Rhodes, Stephen
Schroeder, Marie
Scudiero, Jan
Sloan, Nadine
Stevens, Ted
Stiegman, Glenn
Sturniolo, Mike
Sung, Pei
Teresinski, Doris
Torres-Cabassa, Angel
Tudor, Natalie
Warfield, Diana
Watson, Tony
Weiblinger, Rick
Witten, Celia
Wolf, Beverly
Yahiro, Martin
Yen, Dwight

Division of Ophthalmic and Ear, Nose, and Throat Devices

Alexander, Kesia
Baker, Karen
Beers, Everette
Berman, Sheryl
Boulware, Ashley
Brogdon, Nancy
Brown, Daniel
Burke-Nicholas, Marsha
Callaway, Jan
Calogero, Don
Chen, Tzeng
Cohen, Linda
Cygnarowicz, Teresa
Drum, Bruce
Eydelman, Malvina
Falls, Deborah
Felton, Eleanor
Glover, Joel
Gouge, Susan
Hilmantel, Gene
Hoang, Quynh
Jaffe, Sidney
Jones, Susanna
Kane, James
Kaufman, Daryl
Krawczyk, Claudine
Lepri, Bernard
Leslie, Sharmeka
Lochner, Donna
Malshet, Vasant
McCarthy, Denis
Montgomery, Al
Moore, Shirley
Ortega, Maritze
Romanell, Jake
Rorer, Eva
Rosenthal, Ralph
Saviola, James
Selfon, Eric
Sharpe, Skip
Shi, Dexiu
Shih, Ming-Chuen
Smith, Myra
Storer, Patricia
Thornton, Sara
Toy, Jeffrey
Warburton, Karen
Waxler, Morris
Whipple, David

Division of Reproductive, Abdominal, and Radiological Devices

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Baxley, John
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Chen, John
Cooper, Jeff
Cornelius, Mary Jo
Corrado, Julia
Czerska, Ewa
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Daws-Kopp, Kathryn
Doyle, Bob
Eba, Felissa
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Gonzalez, Gema
Harvey, Brian
Harvey, Elisa
Herrera, Hector
Jevtich, Milorad
Kammula, Raju
Kang, Andrew
Kuchinski, Mike
Lappalainen, Sharon
Lawrence, Lisa
Lutwak, Leo
Mackey, Cheryl
Mallis, Elias
McCool, Barbara
McGee, Leah
Meyers, Catherine
Miller, Linda
Miller, Pat
Mitchell, Diane
Monahan, Jack
Neuland, Carolyn
Nimmagadda, Rao
Nutter, Cathy
O'Brien, Mary Beth
Olvey, Kathleen
Perez, Rod
Phillips, Bob
Pollard, Colin
Price, Veronica
Provost, Miriam
Rubendall, Rita
Sacks, William
Sauls, Mattie
Segerson, Dave
Seiler, Jim
Shuping, Ralph
Virmani, Mridulika
Williams, Dick
Whang, Joyce
Zaremba, Loren
Zaudtke, Peter