OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 2001

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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PREFACE

Dear Reader:

Welcome to our FY 2001 Annual Report. It's a very positive report in many respects. The Office of Device Evaluation approved 53 PMAs last year. This is ten more than we approved in fiscal year 2000 and, in fact, is the largest number approved in any year over the last decade.

Our submission review times are respectable. The PMA turnaround time, based on decision cohorts, is somewhat longer than the previous year's results because we cleared the decks of older PMAs that were on our to-do list. The turnaround times for 510(k)s were actually modestly shorter than those for fiscal year 2000.

Part 1 of the report – ADVANCES IN PATIENT CARE – consists of a selected group of high profile and clinically significant devices approved or cleared in this fiscal year. Each of the six divisions is well represented. These representative medical devices include products used for improved vision, for assisting patients with congestive heart failure, for ease of diagnosis of gastrointestinal disorders and for improved laboratory testing for hepatitis. We hope to add to this list over the coming years with additional innovative and clinically valuable devices.

The remaining parts of the report present key information regarding the numbers and the types of submissions, the review times for each and the comparison with previous years' results. We also list guidances produced and presentations made during the past fiscal year as well as giving a complete roster of ODE staff responsible for the accomplishments during this fiscal year.

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PREFACE

I am indebted to the superb ODE staff professionals and support staff. They have done all the hard work of carefully assessing the many submissions that we receive. I would like to express my appreciation to the other CDRH Offices that provided support and special expertise in the evaluation of premarketing submissions. I also acknowledge the medical device industry that continues to develop innovative products for patient care. Last, but certainly not least, we dedicate this annual report to the patients that will ultimately benefit from all of these devices. Hopefully we serve your needs efficiently and effectively. We want to do the right thing and we want to do it with dispatch.

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.

Now, enjoy the tables, the graphs and the other information found on the following pages.

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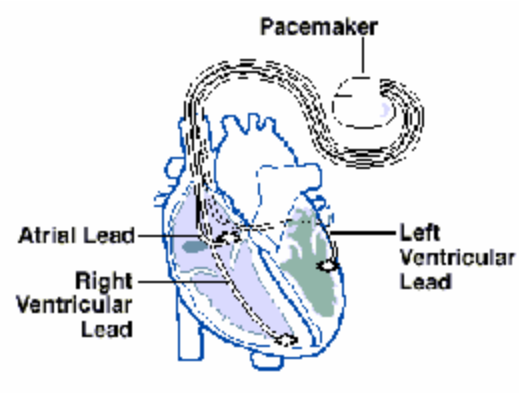
Part 1 – Advances in Patient Care

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 under "Original PMA/HDE Approvals for Fiscal Year 2001." The Premarket Approval Application (PMA) approval website describing recently approved devices with patient information is available at http://www.fda.gov/cdrh/mda/index.html. Below we highlight several medical devices approved or cleared during this past fiscal year that we believe will have a major impact on patient care.

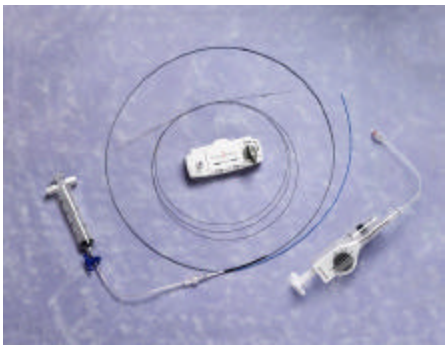
CARDIAC PACING TO TREAT HEART FAILURE – The InSync® Biventricular Cardiac Pacing System including the InSync® Model 8040 Pulse Generator and leads (Attain™ LV Model 2187 and CS Model 2188), *Medtronic, Inc.*, is used to relieve some of the symptoms associated with moderate to severe heart failure in patients who also have an electrical disturbance in the heart that causes the ventricles not to contract at the same time and are not likely to improve with additional drug therapy. Heart failure is a condition where the heart cannot adequately pump blood around the body and may result in shortness of breath or fatigue during exertion. The InSync system consists of the Model 8040 Pulse Generator (which contains a battery and electronic circuitry) connected to three leads (insulated wires) that deliver electrical impulses to stimulate the heart. One lead is placed in an upper heart chamber (right atrium) and the two other leads are placed one in each of the ventricles. The Attain™ LV Model 2187 and CS Model 2188 are specially designed to be positioned within the heart's venous anatomy via the coronary sinus to achieve left ventricular pacing. The therapeutic effect is achieved by simultaneously stimulating the right and left ventricles. The InSync Pacing System is the first pulse generator approved for the treatment of heart failure.



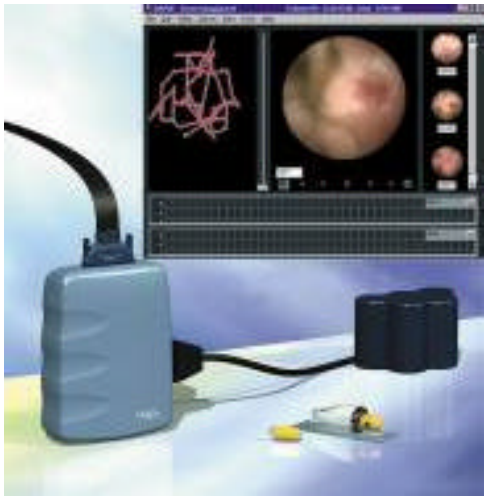
PEDIATRIC EXTERNAL DEFIBRILLATOR – The Heartstream FR2 AED with Attenuated Defibrillation Pads, *Agilent Technologies, Inc. Heartstream Operation,* is the first automatic external defibrillator cleared for use in children less than 8 years of age. It is used in infants and children as a life saving therapy if they suffer sudden death due to ventricular tachycardia or ventricular fibrillation. The Heartstream FR2 AED will be used in the public arena by trained first responder lay people. The device is a system

composed of the FR2 pediatric pads and the defibrillator. The FR2 pads use a component (attenuator) in the connector that automatically absorbs energy from the electrical shock coming out of the AED. This results in delivery of a lower-energy shock that is directed at infants and small children. The reduced dose is 50 Joules instead of the standard 150 Joules usually delivered to adults. The availability of this technology may provide earlier recognition and treatment of ventricular fibrillation, which could in turn improve pediatric cardiac arrest survival rates. These patients can now receive a level of care equivalent to that of adults. Agilent Technologies Inc. will be performing an extensive post-market study to evaluate the use of the device.

EMBOLIZATION PROTECTION DEVICE – The PercuSurge Guardwire Plus, *PercuSurge, Inc., of Sunnyvale, Calif., a division of Medtronic AVE*, is an embolic protection system that is used during interventional cardiology procedures. The device is intended for use on patients who have previously had coronary bypass surgery and whose bypass vein graft has become blocked. These blockages require treatment such as insertion of a stent during angioplasty, which opens up a narrowed vessel. The PercuSurge device consists of a balloon catheter and aspiration catheter. The device is used during these procedures to collect and remove debris created by the interventional treatment thereby preventing blood clots from traveling into the blood stream. The debris--small blood clots, cholesterol crystals, and other particles--may cause serious problems, such as heart attack, if it is swept down the vein graft into the heart.

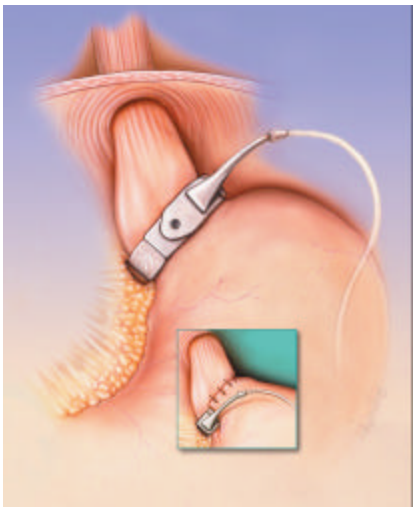


CABLE-FREE ENDOSCOPY – The Given Diagnostic Imaging System, *Given Imaging Ltd.,* is a wireless, cable-free endoscopic imaging device that obtains video pictures from within the small intestine. The major component of the device is a 2.6cm x 1.1cm disposable capsule which contains a miniature metal oxide semiconductor imager, light emitting diode illuminators, and a transmitter with antenna. The capsule is ingested by a patient, traverses the small intestine with the aid of the natural peristaltic activity of the intestinal muscles, and is excreted intact through the rectum. The patient may continue his or her regular ambulatory activities while the capsule is moving through the body. During its passage through the gastrointestinal tract, the camera acquires and transmits images by way of radiofrequency to receiving antennas, which are attached to the patient's torso. The images are then



transferred to a data storage component worn on a belt pack. They are later downloaded and viewed on a computer workstation for interpretation by a physician trained in endoscopy. This device is intended to be used as an adjunctive diagnostic tool in the detection of small bowel mucosal abnormalities.

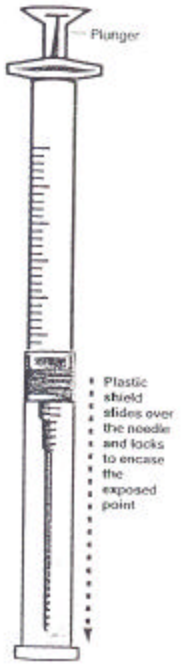
INTRAGASTRIC IMPLANT FOR MORBID OBESITY – The LAP-BAND Adjustable Gastric Banding System, *BioEnterics Corporation*, is a surgically implanted device that includes a silicone elastomer band, access port and kink-resistant tubing. The system is intended for the treatment of severe obesity and is used to induce weight loss by limiting food consumption (restrictive rather than malabsorption). The silicone elastomer band is placed around the stomach to create a restricted opening, (stoma), and a small gastric pouch to limit food consumption and induce early satiety (feeling of fullness). The inner surface of the band is inflatable and connected by the kink-resistant tubing to the access port (a remote injection site). The access port allows non-surgical, percutaneous adjustments (through the surface of the skin) to the stoma diameter. Use of the Lap-Band System is an alternative to conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs and to other surgical options (gastric bypass and vertical banded gastroplasty). Use of this device may result in weight loss in severely obese patients.



GLUCOSE MONITORING WRIST WATCH – The GlucoWatch® Automatic Glucose Biographer from *Cygnus, Inc*., is the first glucose monitoring device that doesn't puncture the skin. Adult diabetics wear the device like a watch where a slight electric current pulls glucose through the skin. Glucose levels are automatically read and recorded every 20 minutes for up to 12 hours. Alarms warn users when high, low, or rapidly declining glucose levels occur. Readings are stored so that users can retrieve them at any time. Patients can better manage their diabetes because they receive information about patterns in their glucose levels. GlucoWatch® results may be similar to finger-stick test results taken at the same time, although some readings will differ significantly from finger-stick tests. GlucoWatch® does not replace finger-stick testing and is not for diabetics below the age of 18.

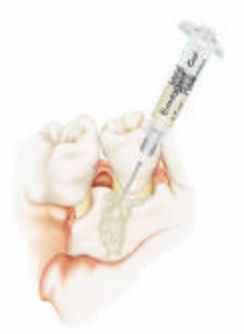
ADVANCES IN PATIENT CARE

MEDICAL DEVICES WITH SHARPS INJURY PREVENTION FEATURES – These medical devices are designed with anti-stick characteristics to aid in the prevention of needlestick injuries. They may incorporate components such as retractable, shielded, blunted, or recessed needles. Other safety devices may include needleless systems such as pre-pierced septa and blunt cannulae and valved connectors (reflux valves). Examples of medical devices now available with a sharps injury prevention feature include: IV administration sets and accessories; piston syringes; hypodermic single lumen needles; IV catheters; blood collection devices; needleless access devices/systems; and vial adapters. Desirable characteristics may include: the device is needleless, the safety feature is an integral part of the device, the device preferably works passively, the user can easily tell if the feature is activated, the feature cannot be deactivated and remains protective through disposal, the device performs reliably, is easy to use and practical, and the device is safe and effective for patient care. A number of States recognize the importance of safety device use and have implemented regulations related to the use of these types of devices. During this fiscal year, General Hospital Devices Branch (GHDB) reviewed a total of 34 medical devices with sharps injury prevention features including 22 shielded needles, 8 needleless devices, and 4 retractable devices.

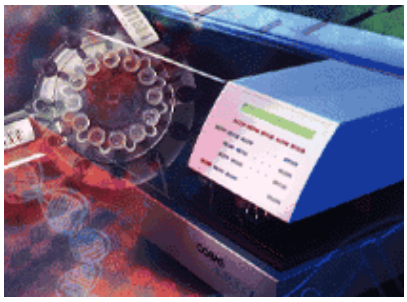


Syringe with protective shield

PERIODONTAL PRODUCT – The Emdogain, *Biora, Inc.,* is a reformulation of a previously approved product that allows a change from the two-vial administration system to an easily applied gel-filled syringe application. Emdogain is approved to treat intrabony periodontal defects and as a topical application to exposed root surfaces where there is moderate to severe periodontal disease. Periodontal disease occurs in many adults and many surgical procedures are performed to treat this disease caused by accumulation of bacteria. The periodontal disease process can affect the gums (gingiva) and the bone that supports the teeth. This Biora product attempts to treat the disease process through a biological approach. This product contains amelogenin that is thought to have an important function in the creation of teeth and their support. Emdogain gel is used with periodontal surgery and leaves a resorbable protein matrix on the root surface. The new formulation allows the dentist to apply the gel without mixing and therefore decreases the time the patient must be in the dental chair.

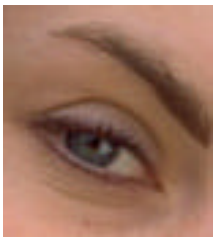


HEPATITIS TESTS – The AMPLICOR™ and COBAS AMPLICOR™ Hepatitis C Virus tests, manufactured by *Roche Molecular Systems, Inc.*, are the first tests approved by FDA for direct detection of hepatitis C virus RNA using nucleic acid amplification. These tests provide highly accurate results for detecting the virus and can establish whether the disease is active and requires treatment.



ADVANCES IN PATIENT CARE

IMPLANTABLE MIDDLE EAR HEARING DEVICE – The Direct, *Soundtec, Inc*., is a surgically implanted hearing device intended to help adults with moderate to severe nerve hearing loss. The implanted portion of the device is a tiny magnet that is attached to one of the middle ear bones. It converts sound to mechanical energy that is directly transferred to the middle ear very much the way normal sound does. The brain interprets the vibrations as sound. This device is different from another implantable middle ear hearing device in that it is minimally invasive. The surgeon goes through the ear canal to place the implant in the middle ear. There are no external incisions. This device is an alternative to traditional hearing aids. Adults who choose this device should have already tried traditional hearing aids and not been satisfied with them.



IMPLANT TO TREAT GLAUCOMA – The AquaFlow Collagen Glaucoma Drainage Device, *Staar Surgical Company,* is used to treat open-angle glaucoma, a condition in which the intraocular pressure is abnormally high. If left untreated, glaucoma can cause blindness. The device is a small cylinder made of collagen. Implanted in the eye, it helps lower the pressure by absorbing excess fluid. The device is designed to maintain a space under the sclera (the white part of the eye). Once placed there, it swells as it absorbs fluid in the eye. This reduces pressure within the eyeball. Later, the device begins to slowly dissolve until it is completely absorbed within 6-9 months. It is the first device that has been approved for use when excess intraocular pressure cannot be completely controlled with medications. Previously cleared glaucoma devices are used only after medications and trabeculectomy surgery has failed. In addition to reducing intraocular pressure, it may allow patients to reduce the number of glaucoma medications they need to control their intraocular pressure.

WOUND AND BURN DRESSING – The OrCel™, *Ortec International,* is a bilayered cellular matrix in which normal human allogeneic skin cells (epidermal keratinocytes and dermal fibroblasts) are cultured in two separate layers into a Type I bovine collagen sponge and serves as an absorbable biocompatible matrix that provides a favorable environment for host cell migration. When OrCel™ is applied to a wound, it serves as a protective wound dressing and provides a favorable environment for the body's cells to grow and secrete various growth factors at the wound site that in turn aid in wound healing. Under the HDE program, OrCel™ is indicated for use in patients with recessive dystrophic epidermolysis bullosa after surgery to correct the "mitten" hand deformities through hand reconstruction. OrCel™ also received PMA approval for use in closure of split

thickness donor site wounds in burn patients. During the autografting procedure, OrCel™ is placed on donor sites to cover the donor site wounds. As healing of donor site wounds in burn patients occurs, it is expected that OrCel™ will dissolve and the patients' own skin cells will replace the OrCel™ cells, creating a new intact skin surface.

SKIN, WOUND AND BURN DRESSING – The DERMAGRAFT®, *Advanced Tissue Sciences,* is a cryopreserved human fibroblast-derived dermal substitute; it is composed of fibroblasts, extracellular matrix, and a bioabsorbable scaffold. It aides the closure of diabetic ulcers of greater than six weeks duration which extend through the dermis, but without tendon, muscle, joint capsule or bone exposure. DERMAGRAFT® should be used in conjunction with standard wound care regimens and in patients that have adequate blood supply to the involved foot.

This dressing can remain on a shelf up to six months when maintained at a temperature of $-75^{o}C \pm 10^{o}$ C. This is a major advantage over similar types of dressings since they usually have a shelf life of approximately five days.

DERMAGRAFT is contraindicated for use in ulcers that have signs of clinical infection or in ulcers with sinus tracts. DERMAGRAFT is contraindicated for use in patients with known hypersensitivity to bovine products, as it may contain trace amounts of bovine proteins from the manufacturing medium and storage solution.

FDA Consumer Web Sites

Publicly Available Device Databases

The Center for Devices and Radiological Health (CDRH) maintains electronic 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. These databases are available in a searchable format to the public.

Consumer Information

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

Website: http://www.fda.gov/cdrh/consumer/index.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

Part 2 – Industry Information

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

During Fiscal Year 2001, no PDPs were completed, but ODE approved 53 PMAs and 4 HDEs. These are listed below. We recommend turning to the 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 2001

		COMPANY	DEVICE
12-Oct-00	P990086	Healthtronics, Inc.	Healthtronics Ossatron
13-Oct-00	P990046	ATS Medical, Inc.	ATS Open Pivot® Bileaflet Heart Valve
16-Oct-00	P000022	Medtronic AVE, Inc.	Medtronic AVE BeStent™ 2 with Discrete Technology™ Over-the-Wire Coronary Stent Delivery System
20-Oct-00	P000015	Cochlear Corp.	Nucleus 24 Auditory Brainstem Implant System
03-Nov-00	P000018	Novoste Corporation	Novoste™ Beta-Cath™ System
03-Nov-00	P990036	Cordis Corporation	Cordis Checkmate™ System
14-Nov-00	P990050	SpectraScience™, Inc.	Optical Biopsy™ System
22-Nov-00	P990056	Roche Diagnostics Corp.	Elecsys® Total PSA Immunoassay
28-Nov-00	P990081	Ventana Medical Systems, Inc.	PATHWAY™ HER 2 (Clone CB 11)
29-Nov-00	P000020	C.R. Bard, Inc.	Stinger® Ablation Catheter and TempLink® Extension Cable
12-Dec-00	P000027	Roche Diagnostics Corp.	Elecysys® Free PSA Immunoassay
21-Dec-00	P970013	St. Jude Medical, Inc.	Microny™ SR+ Model 2425T Pulse Generator
21-Dec-00	P980020	Q-Care International, LLC	Q-103 Needle Management System

05-Jan-01	P000023	TMJ Implants, Inc.	TMJ Fossa-Eminence/Condylar Prostheses
10-Jan-01	H000001	JOMED AB	JOSTENT® Coronary Stent Graft
24-Jan-01	P980044	Seikagaku, Corp.	SUPARTZ™ Dispo
08-Feb-01	P990043	DiaSorin, Inc.	DiaSorin ETI-EBK PLUS Assay
09-Feb-01	P000016	GE Medical Systems Information Tech.	Corometrics Model 120 F-Series Maternal/Fetal Monitor (Fetal Pulse Oximeter)
16-Feb-01	P990085	VISTAKON, Johnson & Johnson Vision	VISTAKON (lenefilcon A) Soft Contact Lenses
21-Feb-01	H990013	Ortec International, Inc.	OrCel™ Composite Cultured Skin
27-Feb-01	P000007	Edwards Lifesciences, LLC	Edwards Prima™ Plus Stentless Bioprothesis Model 2500P
27-Feb-0l	P000035	TMJ Implants, Inc.	TMJ Fossa-Eminence Prosthesis™
22-Mar-01	P990026	Cygnus, Inc.	GlucoWatch® Automatic Glucose Biographer
23-Mar-01	H000004	DePuy Orthopaedics, Inc.	PROSTALAC (Prosthesis of Antibiotic-Loaded Acrylic Cement) Hip Temporary Prosthesis
30-Mar-01	P990038	DiaSorin, Inc.	DiaSorin ETI-MAK-2 PLUS Assay
30-Mar-01	P990041	DiaSorin, Inc.	DiaSorin ETI-AB-EBK PLUS Assay
30-Mar-01	P990042	DiaSorin, Inc.	DiaSorin ETI-AB-AUK PLUS Assay
30-Mar-01	P990044	DiaSorin, Inc.	DiaSorin ETI-CORE-IGMK PLUS Assay
30-Mar-01	P990045	DiaSorin, Inc.	DiaSorin ETI-AB-COREK PLUS Assay
05-Apr-01	P990080	Pharmacia & Upjohn Company	CeeOn™ Edge Foldable Ultraviolet-Absorbing Posterior Chamber Intraocular Lens
18-Apr-01	P000046	Anika Therapeutics, Inc.	STAARVISC II Ophthalmic Viscosurgical Device
20-Apr-01	P980048	Sulzer Spine-Tech	BAK/Cervical (BAK/C®) Interbody Fusion System

20-Apr-01	P000040	BEI Medical Systems, Inc.	Hydro ThermAblator® Endometrial Ablation System
20-Apr-01	P000032	CryoGen, Inc.	HerOption™ Uterine Cryoblation Therapy System
27-Apr-01	P000044	Ortho-Clinical Diagnostics	Vitros Immunodiagnostic Products HBsAg Reagent Pack and Calibrator, and HBsAg Confirmatory Kit
30-May-01	P000037	Medical Carbon Research Institute, LLC	ON-X® Prosthetic Heart Valve Model ONXA
01-Jun-01	P990012	Roche Diagnostics Corp.	Elecsys® HBsAg Immunoassay, Elecsys® HBsAg Confirmatory and Precicontorol HBsAg
05-Jun-01	P000008	BioEnterics Corp.	LAP-BAND® Adjustable Gastric Band
14-Jun-01	P000053	American Medical Systems, Inc.	AMS Sphincter 800™ Urinary Prosthesis
27-Jun-01	P000005	MediTeam AB	Carisolv™ Non-Invasive Dental Caries Removal System
29-Jun-01	P000043	TherMatrix, Inc.	TMx-2000™ and RX-200 BPH Thermotherapy System
03-Jul-01	P000012	Roche Molecular Systems, Inc.	COBAS AMPLICOR Hepatitis C Virus (HCV) Test
05-Jul-01	P000010	Roche Molecular Systems, Inc.	AMPLICOR Hepatitis C Virus (HCV) Test
05-Jul-01	P000021	Dade Behring, Inc.	Dimension® RxL PSA Flex® Regent Cartridge
12-Jul-01	P000026	STAAR Surgical Company	AquaFlow Collagen Glaucoma Drainage Device
12-Jul-01	P000041	Deus Technologies	RapidScreen™ RS-2000
17-Jul-01	P000055	Ferguson Medical	UBIS 5000 Ultrasound Bone Sonometer
20-Aug-01	P000025	Med-El Corp.	MED-EL COMBI 40+ Cochlear Implant System
28-Aug-01	P010015	Medtronic, Inc.	Medtronic® InSync® Biventricular Pacing System including Model 8040 InSync® Pulse Generator, Attain™ LV Model 2187 and Attain™ CS Model 2188 Leads

28-Aug-01	H010001	Avanta Orthopaedics, Inc.	Metacarpophalangeal Joint Implant Finger Prosthesis
30-Aug-01	P010021	Ortho-Clinical Diagnostics, Inc.	Vitros Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrators
31-Aug-01	P010016	Ortec International, Inc.	OrCel™ Bilayered Cellular Matrix
07-Sep-01	P010023	SOUNDTEC, Inc.	SOUNDTEC® Direct System
24-Sep-01	P000029	Q-Med AB	Deflux® Injectable Gel
25-Sep-01	P010017	Fisher Imaging, Corp.	SenoScan® Full Field Digital Mammographic X-Ray System
28-Sep-01	P000036	Advanced Tissue Sciences	Dermagraft®
28-Sep-01	P010013	Novacept, Inc.	NovaSure™ Impedance Controlled Thermal Endometrial Ablation Device

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 01. 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)

Novoste™ Beta-Cath™ System by Novoste Corporation (November 3, 2000)

Cordis Checkmate™ System by Cordis Corporation (November 3, 2000)

Heartstream FR2 AED with Attenuated Defibrillation Pads by Agilent Technologies, Inc. (May 2, 2001)

PercuSurge Guardwire Plus by PercuSurge, Inc. a division of Medtronic AVE (June 1, 2001)

Medtronic® InSync® Biventricular Pacing System by Medtronic, Inc. (August 28, 2001)

Model 3100B High Frequency Oscillatory Ventilator by SensorMedics (September 2, 2001)

Division of Clinical Laboratory Devices (DCLD)

GlucoWatch® Automatic Glucose Biographer by Cygnus, Inc. (March 22, 2001)

COBAS Amplicor Hepatitis C Virus (HCV) Test, version 2.0 by Roche Molecular Systems, Inc. (July 3, 2001)

Amplicor Hepatitis C Virus (HCV) Test, version 2.0 by Roche Molecular Systems, Inc. (July 5, 2001)

Vitros Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrators by Ortho-Clinical Diagnostics, Inc. (August 30, 2001)

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

OrCel™ Bilayered Cellular Matrix by Ortec International, Inc. (February 21, 2001)

OrCel™ Bilayered Cellular Matrix by Ortec International, Inc. (August 31, 2001)

Dermagraft® by Advanced Tissue Sciences (September 28, 2001)

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

AquaFlow Collagen Glaucoma Drainage Device by STAAR Surgical Company (July 12, 2001)

SOUNDTEC® Direct System by SOUNDTEC, Inc. (September 7, 2001)

Division of Reproductive, Abdominal and Radiological Devices (DRARD)

Lap-Band® Adjustable Gastric Banding System by BioEnterics, Corporation (June 5, 2001)

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

DCLD

INSURE Fecal Occult Blood Test by Enterix, Inc. (January 12, 2001)

N Latex Cystatin C by Dade Behring, Inc. (March 13, 2001)

N-Mid Osteocalcin One Step ELISA Model 30SC4000 by Osteometer Biotech A/S (May 16, 2001)

BreathID system for the detection of Helicobacter pylori by Oridion Medical 1987, LTD. (July 9, 2001)

Lipoprotein Test System by Quantimetrix Corp. (July 25, 2001)

DOED

ChromaGen v2.0 Haploscopic System & Color Discrimination Enhancement Soft Contact Lens by Cantor & Silver Ltd. of England (October 20, 2000)

OptiFree Express Multipurpose Disinfecting Solution by Alcon Universal Ltd. (October 23, 2000)

SeronoCem™ Otologic Bone Cement by Corinthian Medical, LTD (February 12, 2001)

Oto-Cem™ Bone Cement by Ototech, Inc. (September 13, 2001)

DRARD

Given® Diagnostic Imaging System (1st swallowable capsule containing a tiny video camera that takes pictures of the entire small bowel) by Given Imaging Ltd. (August 1, 2001)

ODE Guidance Documents

ODE issued 40 guidance documents this Fiscal Year, 29 final and 11 draft, which are listed below. These guidance documents and other previously issued guidance documents are available on the World Wide Web (CDRH homepage: http://www.fda.gov/cdrh) which provides easy access to the latest information and operating policies and procedures and from the Division of Small Manufacturers International and Consumer Assistance (DSMICA, HFZ-200). To contact DSMICA, call

800-638-2041 or 301-443-6597; fax 301-443-8818; Email dsma@cdrh.fda.gov or write to DSMICA (HFZ-200, Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307.) Many guidance documents are also available through the CDRH Facts-On-Demand (faxback service at 800-899-0381 or 301-837-0111).

- Final Guidance Documents Adopted

ODE

Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA; Final Guidance for Industry and FDA Staff (November 02, 2000)

Deciding When To Submit a 510(k) for a Change to an Existing Wireless Telemetry Medical Device; Final Guidance for FDA Reviewers and Industry (November 30, 2000)

Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff (February 28, 2001)

Changes or Modifications During the Conduct of a Clinical Investigation; Final Guidance for Industry and CDRH Staff (May 29, 2001)

Humanitarian Device Exemptions (HDE) Regulation: Questions and Answers; Final Guidance for Industry (July 12, 2001)

DCRD

Guidance for Annuloplasty Rings 510(k) Submissions; Final Guidance for Industry and FDA Staff (January 31, 2001)

Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adapter 510(k) Submissions (November 1, 2000)

Guidance Document for Vascular Prostheses 510(k) Submissions (November 1, 2000)

Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff (November 13, 2000)

Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final Guidance for Industry and FDA (November 29, 2000)

Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA (November 29, 2000)

Investigational Device Exemption (IDE) Study Enrollment for Cardiac Ablation of Typical Atrial Flutter; Final Guidance for Industry and FDA Reviewers (November 8, 2000)

DCLD

Guidance for Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells (November 1, 2000)

Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers (November 30, 2000)

Radioallergosorbent Test (RAST) Methods for Allergen-Specific Immunoglobulin E (lgE) 510(k)s; Final Guidance for Industry and FDA (August 22, 2001)

DDIGD

Guidance on Premarket Notifications for Intravascular Administration Sets (October 12, 2000)

Premarket Approval Application (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA (March 2, 2001)

Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA (March 12, 2001)

DGRND

Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semiconstrained Porous-Coated Uncemented Prosthesis (October 31, 2000)

Guidance for Neurological Embolization Devices (November 1, 2000)

Guidance Document for Dura Substitute Devices (November 9, 2000)

Class II Special Controls Guidance: Polymethylmethacrylate (PMMA) Bone Cement 510(k)s (August 2, 2001)

Guidance for Saline, Silicone Gel, and Alternative Breast Implants (August 13, 2001)

DOED

Information for Keratome Manufacturers regarding LASIK; Final Guidance for Industry (June 21, 2001)

DRARD

Guidance for Investigational Device Exemptions for Solutions for Hypothermic Flushing, Transport, and Storage of Organs for Transplantation; Final Guidance for Industry and FDA Reviewers (January 16, 2001)

Premarket Applications for Digital Mammography Systems; Final Guidance for Industry and FDA (February 16, 2001)

Class II Special Controls Guidance for Home Uterine Activity Monitors; Final Guidance for Industry and FDA Reviewers (March 9, 2001)

Class II Special Controls Guidance Document: Tissue Culture Media for Human ex vivo Tissue and Cell Culture Processing Applications; Final Guidance for Industry and FDA Reviewers (May 16, 2001)

Bone Sonometer PMA Applications; Final Guidance for Industry and FDA (June 21, 2001)

- Draft Guidance Documents for Comment Purposes Only

Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications (November 14, 2000)

Draft Guidance for Prescription Use of Drugs of Abuse Assays Premarket Notifications (November 14, 2000)

Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA (March 1, 20001)

Premarket Approval Applications for In-Vitro Diagnostic Devices Pertaining to Hepatitis C Virus (HCV): Assays Intended for Diagnosis, Prognosis or Monitoring of HCV Infection, Hepatitis C, or Other HCV-Associated Disease; Draft Guidance for Industry and FDA (April 27, 2001)

The Least Burdensome Provisions of the FDA Modernization Act of 1997; Concept and Principles; Draft Guidance for FDA and Industry (May 3, 2001)

Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities (May 21, 2001)

Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff (June 21, 2001)

Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff (July 18, 2001)

A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff (July 25, 2001)

Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Draft Guidance for Industry and FDA (August 15, 2001)

Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis (September 6, 2001)

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 2001 (FY 01). Most of the data discussed below can be found in the tables below and in Part 6 - OPERATIONAL SUMMARY. First, we present the major submissions received and completed. Next, we review the Premarket Approval Applications (PMAs) in terms of review time as well as volume. This same analysis is done for PMA supplements. The remainder of this part deals with Humanitarian Device Exemptions (HDEs), Investigational Device Exemptions (IDEs), and Premarket Notifications (510(k)s).

Resources

ODE ended FY 2001 with 353 employees. During the year, ODE lost 25 full-time employees (18 scientific reviewers, 3 medical officers and 4 clericals) through resignation, reassignment or retirement and added 21 new employees (8 scientific reviewers, 7 medical officers, 1 program analyst and 5 clericals). Through our Intern Program, ODE also had the services of 6 part-time students and professionals.

Workload

During FY 01, ODE received 10,281 major submissions compared to 9,774 major submissions in FY 00. [See Table 1 for a breakdown of major submissions received.]

Table 1. Major Submissions Received
FY 91 – FY 01

TYPE OF SUBMISSION	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
Original PMAs	75	65	40	43	39	44	66	47	60	67	70
PMA Supplements	593	606	395	372	499	415	409	513	552	545	641
Original IDEs	213	229	241	171	214	253	297	322	304	311	284
IDE Amendments	283	297	320	254	210	219	223	226	275	240	206
IDE Supplements	3,647	3,644	3,668	3,020	3,171	3,189	3,776	4,277	4,127	4,388	4,811
510(k)s	5,770	6,509	6,288	6,434	6,056	5,297	5,049	4,623	4,458	4,202	4,248
Original HDE	0	0	0	0	0	0	4	8	12	11	5
HDE Supplements	0	0	0	0	0	0	0	0	4	10	16
Total	**10,581**	**11,350**	**10,952**	**10,293**	**10,189**	**9,417**	**9,824**	**10,016**	**9,792**	**9,774**	**10,281**

On the decision side, ODE completed the processing of 9,954 major submissions, compared to 9,994 major submissions in FY 00. [See Table 2 for major submissions completed.]

Table 2. Major Submissions Completed
FY 91 - FY 01

TYPE OF SUBMISSION	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
Original PMAs	27	12	24	26	27	43	48	46	45	43	53
PMA Supplements	479	394	354	385	435	462	401	421	437	474	442
Original IDEs	220	215	248	174	210	260	272	325	305	320	284
IDE Amendments	287	297	324	256	213	218	220	225	268	251	207
IDE Supplements	3,705	3,469	3,814	3,070	3,181	3,121	3,777	4,209	4,224	4,335	4,803
510(k)s	5,367	4,862	5,073	7,135	7,948	5,563	5,155	5,229	4,593	4,397	4,150
Original HDE	0	0	0	0	0	0	2	4	6	6	4
HDE Supplements	0	0	0	0	0	0	0	0	3	10	11
Total	**10,085**	**9,249**	**9,837**	**11,045**	**12,014**	**9,667**	**9,875**	**10,459**	**9,881**	**9,994**	**9,954**

Premarket Approval Applications (PMAs)

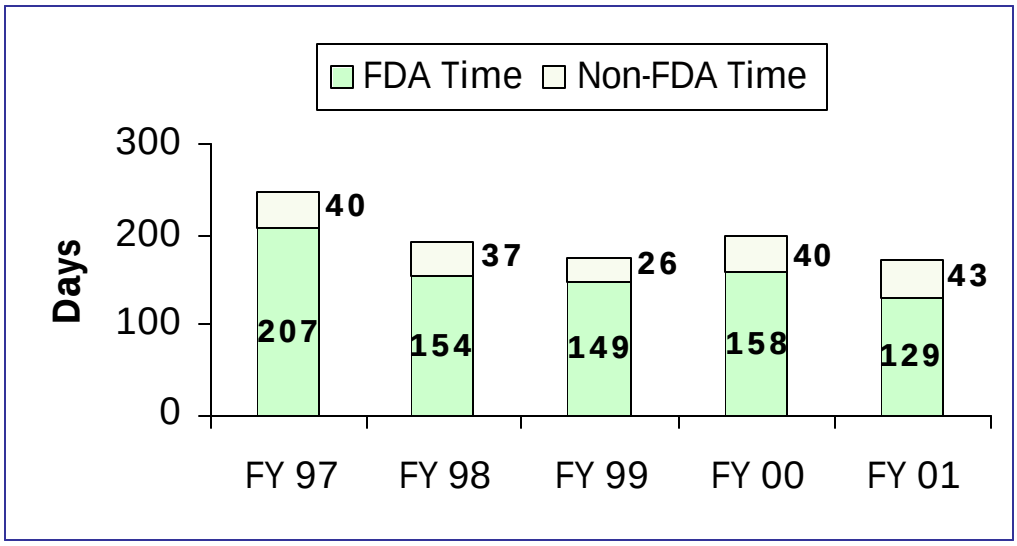
ODE received 70 original PMAs (3 more than the number received in FY 00). The total number of PMAs in inventory (active and on hold) at the end of this fiscal year increased from 76 in FY 00 to 80. The number of active PMAs under review increased at the end of FY 01 to 45 compared to 35 last year, and those on hold decreased from 41 in FY 00 to 35 in FY 01. For the fifth consecutive year, there were no active and overdue PMAs at the end of the fiscal year.

The total number of PMA actions decreased from 321 to 282 actions. These actions included 67 filing decisions, 134 review determinations, and 81 approval/approvable/not approvable decisions.

The 81 original PMA decisions were comprised of 53 approved PMAs, 18 approvable PMAs, and 10 not approvable PMAs. Of the 53 approvals, 11 were expedited PMAs. See Part 2 (INDUSTRY INFORMATION) for a complete list of PMA approvals.

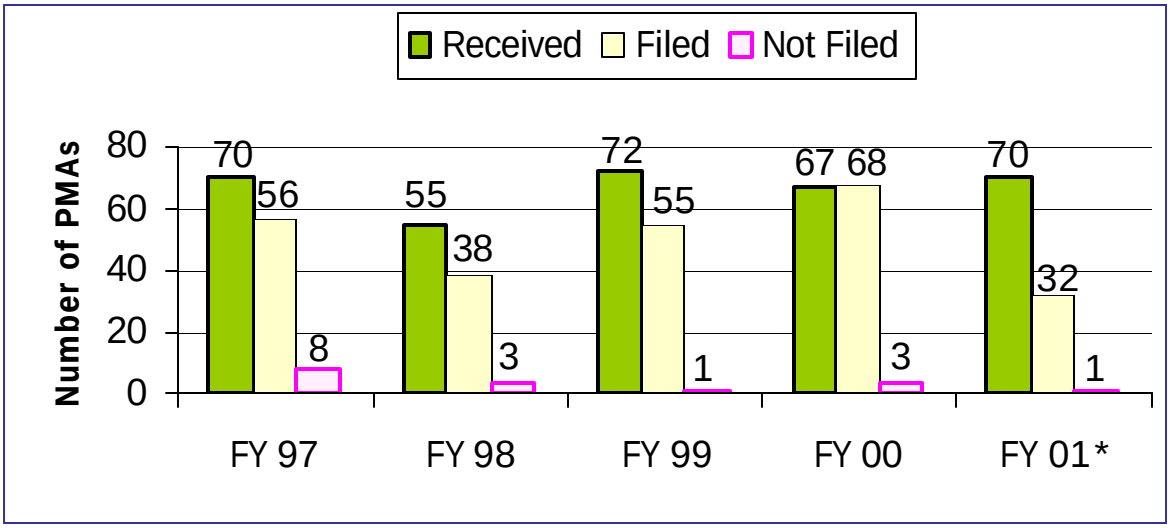
Average FDA review time for original PMAs reaching approval decreased from 158 days in FY 00 to 129 days in FY 01. The non-FDA component of review time increased from 40 days in FY 00 to 43 days this fiscal year. Thus, the total average review time decreased to 172 days from 198 days.

Figure 1. Average Review Time for PMA Decision Cohort Approvals



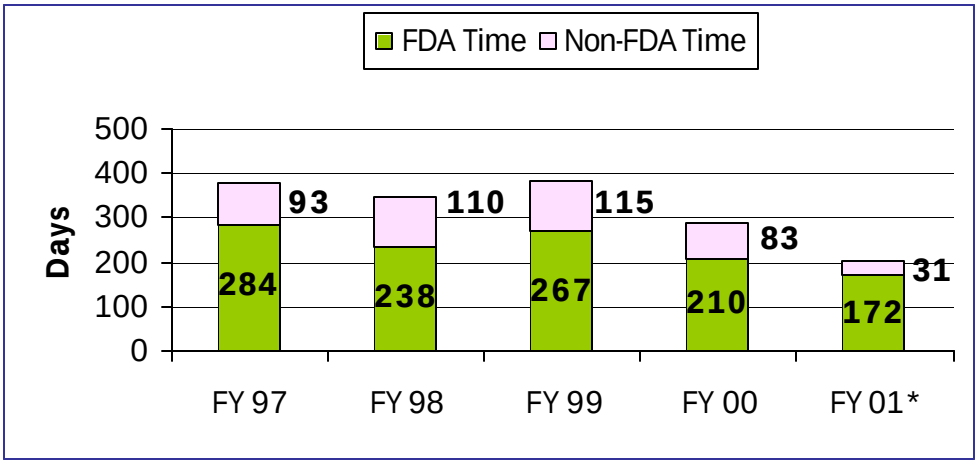
Of greater significance to industry is the total elapsed time from submission to decision. In FY 01, the total average elapsed time for PMA decision cohort performance increased from 363 days in FY 00 to 411 days in FY 01. (Please refer to Table 4.)

Figure 2. Original Receipt Cohort PMAs Received and Filed



*First six months

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



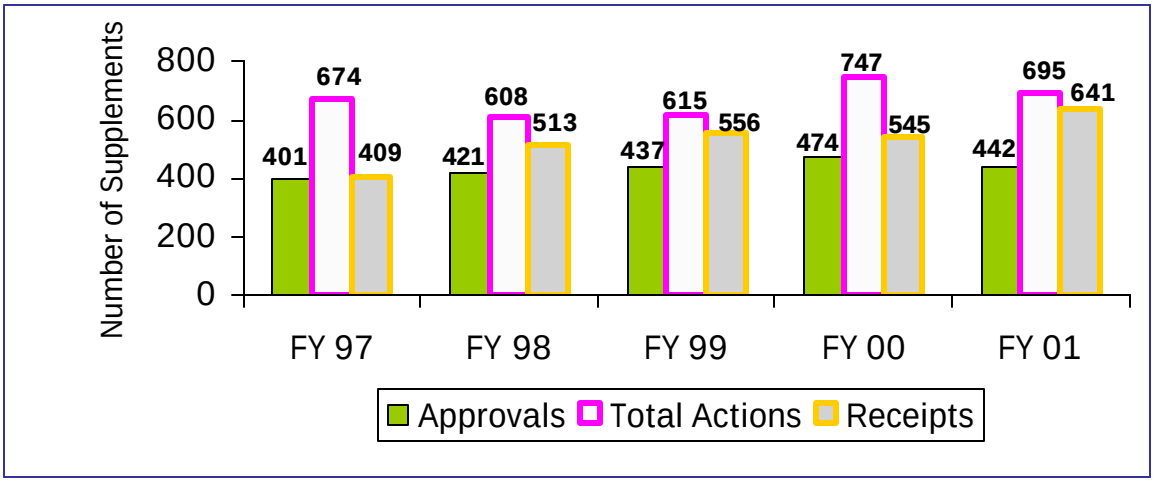
*First six months

For the first 6 months of FY 01 for PMA receipt cohort performance, the average FDA days from filing to first action increased from 132 in FY 00 to 133 days.

The average FDA (total) elapsed time to an approval or to a denial decreased from 210(293) in FY 00 to 172(203) days in FY 01 (see Figure 3). The median FDA (total) elapsed time to an approval or denial decision decreased from 180(252) in FY 00 to 177(188) days in FY 01. This means that all of the statistics of the PMA receipt cohort for FY 01 indicate that we are making decisions faster.

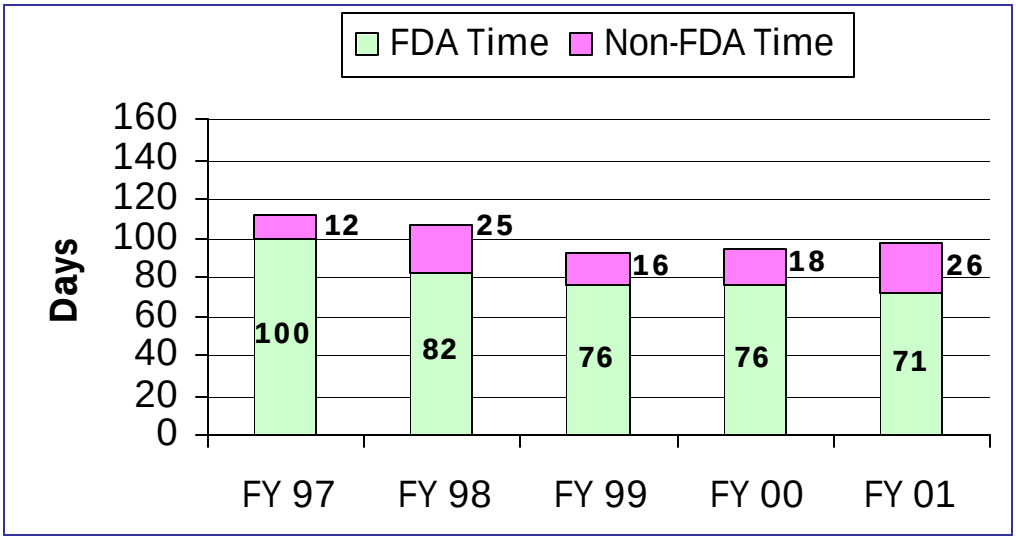
The number of PMA supplements received increased from FY 00's 545 to 641in FY 01. There were 695 PMA supplement actions which is down from last year's 747 total actions. These actions included 14 panel track PMA supplement filing decisions, 87 scientific review decisions, and 594 approval decisions (see Figure 4).

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



For PMA supplements reaching final action, the average total review time increased from 94 days in FY 00 to 97 days in FY 01, and the average total elapsed time decreased from 122 days to 110 days (see Figure 5).

Figure 5. Average Review Time for PMA Supplements



Unlike in FY 97, FY 98, FY 99 and FY 00, there were 6 PMA supplements active and overdue at the end of this fiscal year. The number of active supplements increased to 152 in FY 01 from 98 in FY 00, and the number of supplements on hold increased from 84 to 94. We received about 100 more PMA supplements and are reaching final decisions on more, but we are taking an average of 5 fewer days for the decisions.

For the first 6 months of FY 01 for PMA supplements receipt cohort performance, the first action and final action as follows. The average FDA days from filing to first action increased from 63 in FY 00 to 71 days in FY 01. The average FDA (total) elapsed time to an approval or denial remained the same from 65(81) in FY 00 to 65(72) in FY 01. The median FDA (total) elapsed time to an approval or denial increased from 32(40) in FY 00 to 37(43) days in FY 01.

Real-Time Review of PMA Supplements

A total of 162 requests were received and processed for real time PMA supplements in FY 01 which represents 25% of all supplements received. Of those submissions, 131 were approved. Most applicants chose telephone conferencing versus a face-to-face meeting or a videoconference. The majority of these applications were reviewed in DCRD (63%) followed by DGRND (21%), DOED (5%), DRARD (5%), DCLD (4%) and DDIGD (2%). Overall, average review time from receipt to first action (approvable, not approvable or approval order) was 53 days, and was 50 days from receipt to final approval.

Product Development Protocols (PDPs)

No original PDPs nor "Real Time" PDP supplements were approved in FY 01. Seven 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 interested applicants to fully evaluate their PMA options.

Modular PMA Review

For FY01 ODE received a total of 37 PMA shells and 32 modules. A total of 7 modules were found to be acceptable while 8 received deficiency letters. A number of modules were rolled into PMA review during FY 01 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 slightly lower than 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 5 original HDEs, 6 less than the number received in FY 00. The total number of original HDE actions decreased from 36 in FY 00 to 30 in FY 01. These actions included 7 filing decisions, 15 review determinations, 4 approval decisions and 4 other final decision.

A total of 6 first actions were made this fiscal year, a decrease from 8 made last year. The average time from filing to first action decreased from 61 days in FY 00 to 42 days in FY 01.

One hundred percent of the first actions made in FY 01 occurred within 75 days.

The 4 approval decisions were comprised of 4 approved HDEs and no approvable HDEs.

In FY 01, the average elapsed time (from filing to final approval) for original HDEs was 243 days, an increase from 216 days in FY 00. The average FDA time was 143 days, an increase from 112 days in FY 00. The average non-FDA time was 100 days, a decrease from 104 days last year.

The total number of original HDEs in inventory (active and on hold) at the end of this fiscal year was 7. Of these, 1 was under review and 6 were on hold. There were no active HDEs that were overdue at the end of the fiscal year.

The number of HDE supplements received increased from 10 in FY 00 to 16 in FY 01. There were 15 HDE supplement actions in FY 01, up from 11 in FY 00. These actions included 11 approval decisions and 1 not approvable decision.

A total of 12 first actions for HDE supplements were made this fiscal year, an increase from 10 last year. The average time from filing to first action increased from 44 days in FY 00 to 52 days in FY 01. Sixty-seven percent of the first actions were made within 75 days.

The average elapsed time (from filing to final approval) for HDE supplements decreased from 76 days in FY 00 to 46 days in FY 01. The average FDA time increased from 43 days in FY 00 to 46 days in FY 01. Non-FDA time decreased from 33 days in FY 00 to no days in FY 01.

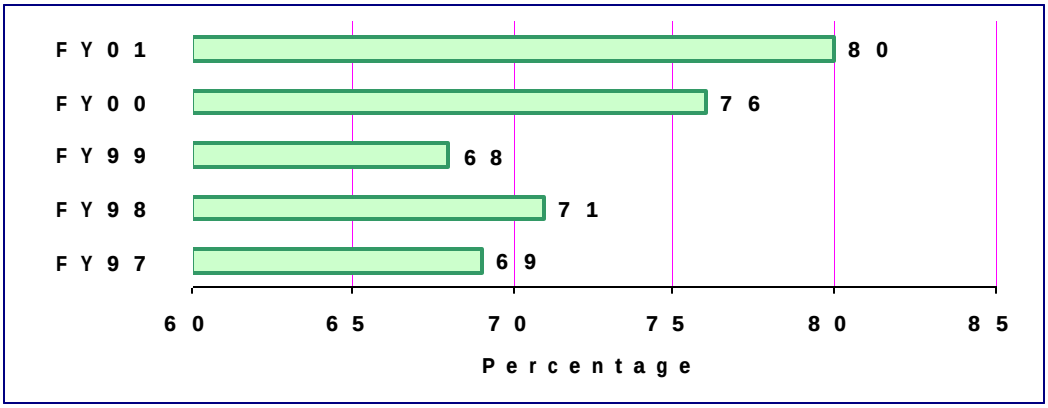
The number of HDE supplements in inventory (active and on hold) at the end of this fiscal year was 5. Of these, 4 were under review and 1 was on hold. There were no active HDE supplements that were overdue at the end of the fiscal year.

Investigational Device Exemptions (IDE)

During FY 01, ODE reviewed 287 pre-IDEs. Based on these reviews, guidance for the pre-original IDE submissions were provided through meetings with the sponsors, letters, fax, or by phone.

ODE received 284 original IDEs, a decrease from 311 received in FY 00. There were 284 decisions made on original IDEs, a decrease from 320 last year. One hundred percent of all original IDE decisions were issued within 30 days in FY 01. 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 76% in FY 00 to 80% in FY 01 (see Figure 6).

During this fiscal year, 206 IDE amendments were received. Decisions were made on 207 amendments: 73 approvals (35%); 39 disapprovals (19%); and 95 other administrative actions (46%). Ninety-nine percent of these decisions were made within 30 days.

It took an average total time of 141 days to approve IDEs that were initially disapproved, up from 136 days in FY 00. This average approval time consisted of 59 days for FDA time, down from 70 days last year, and 82 days for non-FDA time, up from 66 days in FY 00.

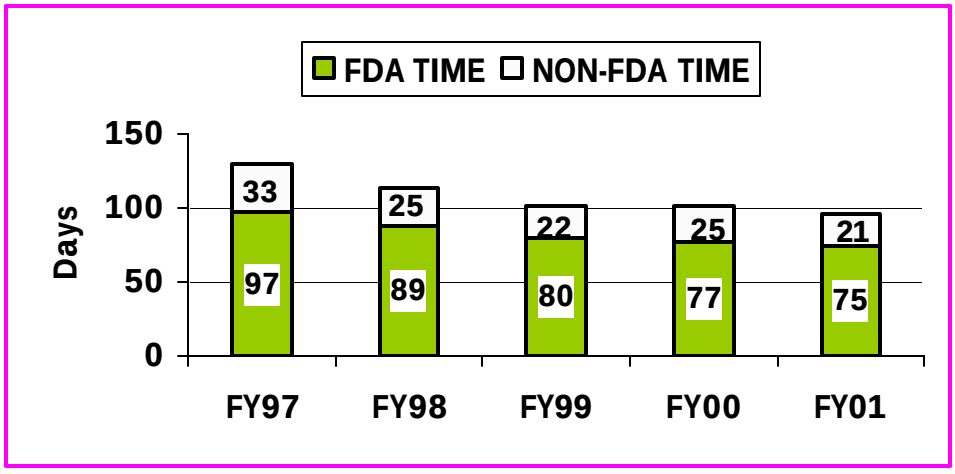
ODE received 4,811 IDE supplements during FY 01. There were no overdue supplements at the end of the year, and the percentage of supplements reviewed within the 30-day statutory timeframe was 100 percent in FY 01. The average review time for IDE supplements was 21 days, up from 20 days in FY 00.

Premarket Notification (510(k)s)

ODE received 4,248 original 510(k)s, as well as 1,579 510(k) supplements (responses to hold letters, the receipt of which restart the 90-day review clock), and 2,620 510(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 decreased to 96 days in FY 01 from 102 in FY 00, and the average FDA review time was 75 days, down from 77 days in FY 00. 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 and FY 01.

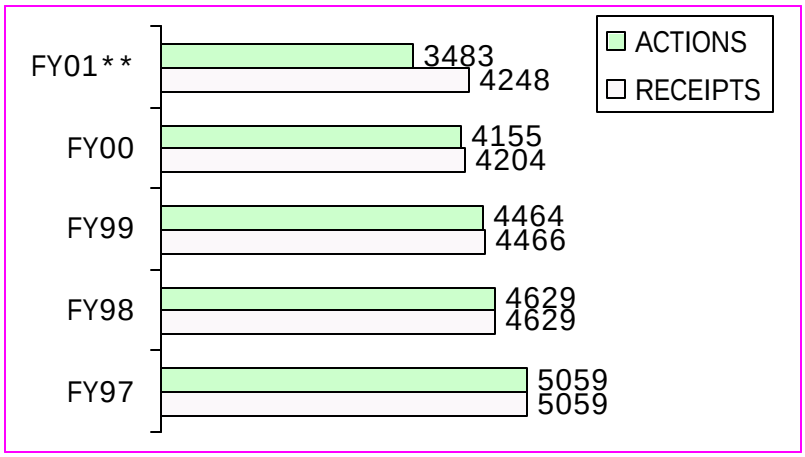
Figure 7. Average 510(k) Review Time for Decision Cohort



There were 1,316 510(k)s in inventory (those under active review or on hold) at the end of this fiscal year. The number on hold at the end of FY 01 was 382. Most important, for the sixth consecutive fiscal year there were no 510(k)s active and overdue at the end of the reporting period.

For the first 9 months of FY 01 for receipt cohort performance, the FDA time from receipt to final decision was 65 days.

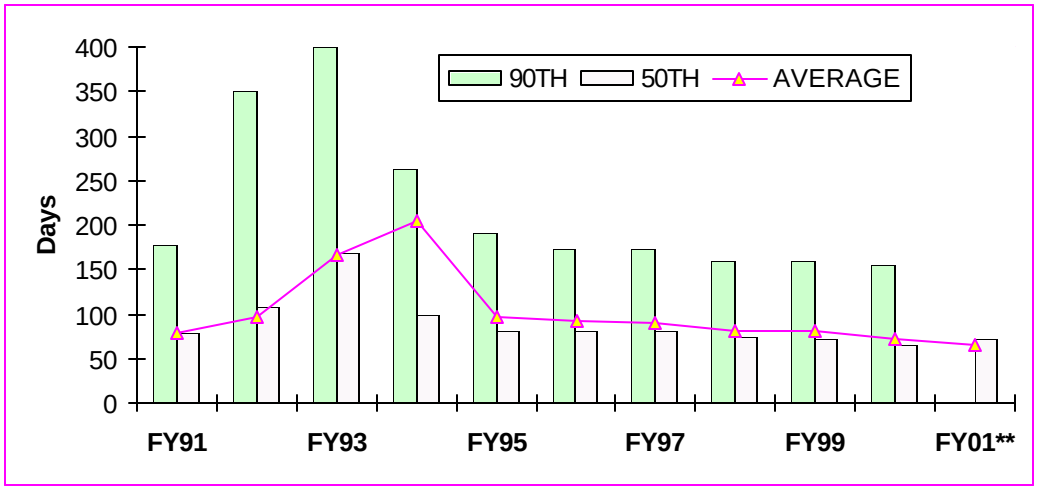
Figure 8. Receipts and Actions for 510(k) Receipt Cohorts*



*Cut Off Date of 9/30/01 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 remained 75 days.

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



*Cut Off Date as of 9/30/01 for all receipt cohorts.
**For the first 9 months of FY 01. 90th percentile data not available for FY 01.

Third-Party Review of 510(k)s

During fiscal year (FY) 2001, ODE received 107 510(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 128-percent increase over the 47 such submissions received by ODE last fiscal year. ODE made final decisions on 99 "third party" 510(k)s in FY 2001, an increase from the 46 final decisions in FY 2000. 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 65 days, as compared to the average total elapsed time of 91 days for ODE's decisions on comparable 510(k)s that did not have a third-party review.

In the *FEDERAL REGISTER* of March 8, 2001 (66 FR 13936), the Center announced an expansion pilot that permits third-party review of 510(k) submissions for a greatly expanded list of devices. The pilot allows—subject to certain specified conditions—third-party review of approximately 460 Class II devices for which device-specific guidance does not exist. Previously, device-specific guidance existed for each Class II device that was eligible for third-party review. The expansion more than tripled the number of eligible devices, increasing the total from 211 devices to more than 670. 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, 2000 to September 30, 2001 ODE received 717 *Special* 510(k)s out of the 4,248 total number of 510(k)s received, and 685 have received final decisions with the average FDA review time of 28 days and the average total time of 32 days, and 643 were found substantially equivalent, 3 were found not substantially equivalent, and the remaining 39 had other decisions such as withdrawn or deleted.

Abbreviated 510(k)s

During this fiscal year, ODE received 174 *Abbreviated* 510(k)s out of the 4,248 total number of 510(k)s received. One hundred seventy-four received final decisions (147 substantially equivalent, 1 not substantially equivalent, and 26 other decisions) with a FDA average review time of 82 days and total time of 99 days. None of the *Abbreviated* 510(k)s went over 90 days.

Significant Medical Device Breakthroughs

During FY 01, ODE approved 16 PMAs and cleared 10 510(k)s that represent significant medical device breakthroughs. See Part 2 - INDUSTRY INFORMATION, Significant Medical Device Breakthroughs - for a complete listing.

Classification Actions

- Published a final rule in the *Federal Register* on May 16, 2001 classifying Tissue Culture Media for Human Ex Vivo Tissue and Cell Culture Processing Applications into Class II.

- Published a final rule (technical amendment) in the *Federal Register* on May 22, 2001 classifying Pedicle Screw Spinal Systems into Class II.

Automatic Evaluation of Class III Designation

- Issued an order on November 13, 2000 classifying Triage B-Type Natriuretic Peptide (BNP) Test into Class II.

- Issued an order on December 5, 2000 classifying Dulbecco's Modified Eagle Medium "DMEM" into Class II.

- Issued an order on June 11, 2001 classifying the Given Diagnostic Imaging System into Class II.

Proposed Reclassification Actions

- Published a proposed rule in the *Federal Register* on May 9, 2001 to reclassify Automated Differential Cell Counters from Class III into Class II.

- Published a proposed rule in the *Federal Register* on August 15, 2001 to reclassify the Endolymphatic Shunt Tube with Valve from Class III into Class II.

- Published a proposed rule in the *Federal Register* on September 6, 2001 to reclassify the Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis from Class III into Class II.

Reclassification Actions

- Published a final rule in the *Federal Register* on October 10, 2000 reclassifying Endosseous Dental Implant Accessories from Class III into Class II.

- Published a final rule in the *Federal Register* on February 28, 2001 reclassifying the Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis from Class III into Class II.

- Published a final rule in the *Federal Register* on March 9, 2001 reclassifying the Home Uterine Activity Monitor from Class III into Class II.

- Published a final rule in the *Federal Register* on April 10, 2001 reclassifying Six Cardiovascular Preamendments Class III Devices into Class II.

- Published a notice in the *Federal Register* on April 30, 2001 denying the petition to reclassify the Totally Implanted Spinal Cord Stimulator.

- Issued a reclassification order on September 4, 2001 reclassifying the Absorbable Polydioxanone Surgical Suture from Class III into Class II.

Class II Exemption Petitions

- Published a Class II exemption in the *Federal Register* on October 18, 2000 for Total Triiodorthyronine Test System submitted by Abbott Laboratories.

- Published a Class II exemption in the *Federal Register* on December 8, 2001 for Catheter, Retention, Barium Enema submitted by E-Z-EM, Inc.

- Published a Class II exemption in the *Federal Register* on March 21, 2001 for Pharmacy Compounding System submitted by Baxter HealthCare, Corporation.

- Published a Class II exemption in the *Federal Register* on September 18, 2001 for F Spoon Fluoroscopic Accessory submitted by the F Spoon Company.

Final 515(b) Calls for PMAs

There were no calls for PMAs in FY 01.

Part 4 – Major Program Initiatives

Bioterrorism Preparedness

ODE is currently involved in several resource-intense initiatives related to national bioterrorism preparedness and response. ODE established liaison and collaboration with other government agencies and the military to prepare for regulatory responsibilities applicable to in vitro diagnostic products and other medical devices that are critical to bioterrorism preparedness efforts. ODE is also developing a pool of expert reviewers to meet the expected demands related to timely premarket review and approval of these devices.

Although ODE has been involved in CDRH bioterrorism preparedness activities in the past, during this fiscal year our involvement intensified to the point that it has become a major program initiative. These activities cover several ODE divisions and different aspects of the problem.

The Division of Clinical Laboratory Devices (DCLD) formed the DCLD IVD Chem-Bioterrorism preparedness Working Group to develop a clear interpretation of the IVD regulations for supporting CDC's and the military's bioterrorism preparedness activities. The medical and public health preparedness and response to bioterrorism threats include the identification of threat agents by using in vitro diagnostic devices. Most laboratory reagents and test kits used for the identification of threat agents are not routinely used in the clinical laboratory and have not been cleared or approved by FDA.

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

The Division of Dental, Infection Control, and General Hospital Devices (DDIGD) evaluated a modification of a device intended for use by the military to remove chemical agents from clothing and skin. It also began discussions with another applicant on a device intended for the same use but employing a different formulation. DDIGD evaluated submissions during the fiscal year on liquid chemical agents, ultraviolet light air purifiers, and sterilizers that could be used to decontaminate surfaces and products.

The Division of Cardiovascular and Respiratory Devices (DCRD) has been involved in the Ad Hoc Committee on Device Shortage for Bioterrorism Preparedness and Response. The Committee considered a list of devices that would be needed in the event of a chemical or biological attack.

POS is also involved in bioterrorism preparedness and response by providing support to the ODE Divisions that are directly involved. In particular, the IDE staff has been very helpful by providing guidance on difficult regulatory issues.

Genetics Testing

During FY O1, three agencies within HHS (the FDA, the Centers for Disease Control and Prevention (CDC), and the Center for Medicare and Medicaid Services (CMS)) have been collaborating on the Department's role in the oversight of genetic testing. In response to the Secretary's Advisory Committee on Genetic Testing (SACGT) recommendations, ODE's Division of Clinical Laboratory Devices has under development a "Genetics Template" which will serve as an outline for collecting administrative, analytical, and clinical data on tests used to detect the presence of genetic diseases. DCLD has been developing this template in collaboration with professional laboratory and clinical organizations. Additional steps for the potential oversight of genetic disease testing are still in the planning stages, but information collected in the templates could enable FDA to focus its attention to monitoring genetics testing activities.

Part 5 - Program Support

Guidance for Industry and Reviewers

In FY 01, ODE published 29 final guidance documents and published 11 draft guidance documents for comment. See INDUSTRY INFORMATION for a complete listing of all ODE guidance documents published in FY 01.

Least Burdensome

A central purpose of the Food and Drug Administration Modernization Act of 1997 (FDAMA) was to ensure the timely availability of safe and effective new products that would benefit the American public. While Congress wanted to reduce unnecessary burdens associated with the premarket clearance and approval processes, Congress did not intend to lower the statutory thresholds for substantial equivalence or reasonable assurance of safety and effectiveness. To help achieve this goal, Congress added sections 513(a)(3)(D)(ii) and 513(i)(1)(D) to the act.

These two sections of the law contain what are commonly referred to as the "least burdensome provisions" of the act. During the last couple years, CDRH has been working with the Least Burdensome Industry Task Force to develop an interpretation of the least burdensome provisions that would accurately capture Congress' intent and that could be implemented consistently by the agency and industry. Recently, a draft guidance was issued entitled, "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles." As presented in this guidance, the agency considers the least burdensome concept to be one that could affect almost all premarket regulatory activities, including presubmission meetings with industry, premarket submissions, and the development of guidance documents and regulations.

The Level 1 draft was made available in the May 3, 2001 *Federal Register*, and the 90-day comment period for the draft ended on August 1, 2001. While almost all of the comments strongly supported the guidance and encouraged full implementation of it as soon as possible, several comments included recommendations for the agency. For example, it was recommended that FDA develop a training program for its staff on the least burdensome approach as well as ways to assess both the agency's success in implementing the principles and industry's satisfaction with FDA's incorporation of them into its daily activities. The agency agrees with many of these recommendations and has incorporated them into the guidance that is currently being finalized.

The agency has also developed several other guidances to contribute to the least burdensome effort. These include the guidance entitled, "Early Collaboration Meetings under the FDA Modernization Act (FDAMA)." A listing of all of the Center's least burdensome activities can be found on the Least Burdensome website at: www.fda.gov/cdrh/modact/leastburdensome.html.

Significant Jurisdictional Issues

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

In FY 01 CDRH participated in the review of 27 out of 30 (three were assigned wholly to CDER and CBER only) RFD's received by the FDA's Ombudsman's Office, in addition to completing the review of 7 RFDs received in FY 2000. The reviews of the 27 new requests were assigned to the ODE Divisions as follows; DDIGD was assigned 10 (ten) to review, DCRD was assigned to review 7 (seven), DGRND was assigned 5 (five), DRARD was assigned 4 (four) and DOED was assigned 1 (one). DCLD was not assigned any RFDs to review.

Out of the 27 FY 01 RFDs assigned to CDRH for review, 9 (nine) were not due for completion until FY 02. Of the RFD's whose reviews were completed, CDRH was assigned the lead center in 8 of those requests and 2 (two) were withdrawn before their review could be completed. Of the remaining RFDs the lead center designation was to either CDER (7) or CBER (1).

CLIA Activities

Congress passed the Clinical Laboratory Improvement Amendments in 1988, establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The categorization of commercially marketed *in vitro* diagnostic tests under CLIA has been the responsibility of the FDA since February 2000. DCLD performs the CLIA complexity categorization that includes the assignment of these test systems to one of three CLIA regulatory categories (high, moderate and waived) based on their potential risk to public health. During FY01 DCLD performed categorizations on 132 High, 1962 Moderate, and 149 Waived tests. FDA, CDC, and CMS are working together to publish a final rule on CLIA standards. More information on the CLIA program can be found at http://www.fda.gov/cdrh/clia/index.html.

Advisory Panel Activities

The Office of Device Evaluation's Medical Devices Advisory Committee (MDAC) with its 18 panels provide clinical and scientific advice to FDA in several areas of activity fundamental to the regulation of medical devices. The most significant of these areas of activity are: (1) classification and reclassification of medical devices into one of three classes based on risk,

(2) review and make recommendations on premarket submissions such as Premarket Approval Applications (PMAs), Product Development Protocols (PDPs), and Premarket Notification submissions (510ks), (3) provide advice on guidance documents which convey to industry and the agency staff FDA's expectations for studies and data for premarket review, and (4) provide input on issues or problems concerning the safety and effectiveness of medical devices.

In FY 01, ODE held 23 panel meetings. The panels reviewed and made recommendations on: 20 PMAs, 1 PMA supplement, 2 510(k)s, 2 reclassification petitions, and 8 general issues. The Dispute Resolution panel met twice: (1) to discuss a PMA and (2) to discuss a general issue. CDRH conducts training sessions for new panel members and consultants prior to their participation on a panel. In FY01, there were 19 training sessions for new members. The panels reviewed PMAs for significant medical device breakthrough technologies such as a collagen glaucoma drainage device, a embolic radiation therapy device, a percutaneous myocardial revascularization system, and an interactive wound and burn dressing.

A new draft guidance document, "Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Meetings" issued for comment on July 18, 2001. This guidance document describes the process that CDRH intends to follow when making materials that are sent to advisory panel members publicly available. The website for this draft guidance document is: http://www.fda.gov/cdrh/ode/guidance/1341.html.

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.

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

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

ODE Integrity Program

During this fiscal year, ODE considered about 51 cases concerning the integrity of data submitted to the agency in premarket applications. Under the Application Integrity Program (AIP), one firm was placed on the AIP list and AIP restrictions applied against this firm. AIP restrictions were removed from one firm during the fiscal year.

ODE handled 39 instances related to questions arising under the standards of conduct for employees. During FY 01, 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/forms_pubs_otherdocs/fpo_files/reference/rfsoc_99.pdf).

Freedom of Information Requests

ODE staff received 868 FOI requests during FY 01, a decrease from 1,080 in the last fiscal year. During FY 01, the number of FOI requests closed was 1,048 compared to 1,146 in FY 00. The total number of FOI requests pending in ODE at the end of FY 01 is 420 compared to 621 in FY 00.

Congressional Inquiries

Congressional interest in ODE programs continued to be strong in FY 01. ODE staff responded to inquiries and participated in briefings on such topics as breast pumps, excimer lasers, Temporomandibular joint (TMJ), condom labeling, reuse, hip replacement, cosmetic facial stimulator, and 510(k) rescission proposed rule. ODE also participated in Congressional hearings held during FY 01 dealing with FDA's budget, FDAMA, and reuse of medical devices labeled for single use.

Publications

During FY 01, ODE staff authored 31 manuscripts for publication in professional and scientific journals and delivered 56 presentations at professional, scientific and trade association meetings. See Appendix B for a bibliography of publications.

ODE Vendor Day

In FY 01, ODE, in conjunction with the Orthopedic Surgical Manufacturers Association (OSMA), sponsored one Vendor Day - an informative exhibit and exchange seminar

with eleven device manufacturers on Total Anthroplasty, Fracture, Spine, and Other Devices.

Site Visits

In FY 01, 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 various medical device manufacturing firms but also to hospitals for the observations of certain devices in use. As a result, eleven firms and/or hospitals were visited to learn about innovative surface modifications, implantable middle-ear hearing aids, knee resurfacing, heart valves, and other devices.

Mentoring Program

ODE's mentoring program is designed to orient new employees to their job responsibilities and their workplace. The program matches 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 01, ODE continued the ODE Intern Program that allows 4-5 college students and/or professionals to work in a regulatory agency. The students gain entry level professional "real work" experience; the professionals gain experience working in a government regulatory environment; and both groups work alongside some of the agency's top healthcare authorities. Special attention is given to minority candidates. There were six (6) participants in the FY 01 program.

ODE continues to expand 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. Three center employees participated in FY 01.

Minority Recruitment

To enhance the center's effort to increase the hiring of minorities and those with a disability, ODE participated in the 2001 National Employment Fair for Persons with a Disability; OPM's 2001 Strategic Compensation Conference and the Department's Hispanic Employment Forum.

Computer Tracking Systems

ODE tracking system changes included premarket database enhancements, revised report and query programs, and modifications to the division level tracking system. In addition, enhancements were made to the CLIA tracking system to collect applicant contact information, to identify the CLIA data that should be updated and to produce new reports. Programs were modified to produce files of Third Party Accredited Persons to be placed on the Web, capture an indication of a "remanufactured device" in the IDE data entry program and add an indication of third party review to several 510k reports. All of the database modifications and data synchronization required to support the reorganization of DCLD in ODE were implemented.

Office Automation

After extensive equipment improvements in Fiscal Year 2000, ODE continued to make equipment improvements in Fiscal Year 2001 but on a smaller scale. ODE prepared PCs for a future upgrade to Windows 2000 and Microsoft Office 2000 with memory enhancements and also developed a plan to replace older and slower PCs. ODE installed Acrobat 5.0 on all PCs to allow greater flexibility in working with submissions in the PDF format, and to ensure compatibility with newer versions of IMAGE (CDRH's document archival system). ODE tested a new dialin system for ODE users, resolved problems with the new system and developed dialin solutions for WindowsNT and Windows 2000 users.

Electronic Submissions

In Fiscal Year 2001, ODE received 156 electronic submissions for PMAs, IDEs, HDEs and 510(k)s from 47 different sponsors. In some cases, 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. For Fiscal Year 2002, ODE will revise its definition of electronic submission to represent submissions where a copy of the entire submission arrives at ODE in electronic format. 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

CDRH has the ability to conduct Room and Desktop Video Conferences with outside parties that have H.320 compliant systems, a standard for video conferencing over ISDN lines and other narrowband transmission media. In Fiscal Year 2001, 9 video conferences were held involving industry, other Federal agencies and for internal use.

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/guidance.html. The database is searchable by words in the document title, office, division, or any combination of these elements. In Fiscal Year 2001, ODE posted 40 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 International and Consumer Assistance (DSMICA) 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: dsmica@cdrh.fda.gov
Phone: Toll Free 1-888-463-6332 or 301-827-3990 directly between the hours of 8:00 a.m. – 4:30 p.m. EST

Part 6 – 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 17) and 2 (page 18) for general summary of major submissions received and completed.

Table 3. PMA/HDE/IDE/510(k) Submissions Received FY 97 - FY 01

TYPE OF SUBMISSION	NUMBER RECEIVED				
	FY97	FY98	FY99	FY00	FY01
Premarket Approval (PMAs)					
Original Applications	66	47	60	67	70
Amendments	829	710	767	978	753
Supplements	409	513	552	545	641
Amendments to Supplements	819	863	924	932	918
Reports for Original Applications	435	431	406	419	492
Reports for Supplements	2	0	0	0	0
Master Files	130	94	25	44	36
PMA Subtotal	**2,690**	**2,658**	**2,734**	**2,985**	**2,910**
Humanitarian Device Exemptions (HDEs)					
Original Applications	4	8	12	11	5
Amendments	10	32	55	56	62
Supplements	0	0	4	10	16
Amendments to Supplements	0	0	3	12	8
Reports for Original Applications	0	0	6	9	24
Reports for Supplements	0	0	0	0	0
HDE Subtotal	**14**	**40**	**80**	**98**	**115**
Investigational Device Exemptions (IDEs)					
Original Applications	297	322	304	311	284
Amendments	223	226	275	240	206
Supplements	3,776	4,277	4,127	4,388	4,811
IDE Subtotal	**4,296**	**4,825**	**4,706**	**4,939**	**5,301**
Premarket Notification (510(k)s)					
Original Notifications	5,049	4,623	4,458	4,202	4,248
Supplements	2,785	2,023	1,872	1,742	1,579
Amendments	4,433	3,692	2,962	2,953	2,620
510(k) Subtotal	**12,267**	**10,338**	**9,292**	**8,897**	**8,447**
PMA/HDE/IDE/510(k) Total	**19,267**	**17,861**	**16,812**	**16,919**	**16,773**

Table 4. Original PMA Decision Cohort Performance*
FY 97 - FY 01

	FY 97	FY 98	FY 99	FY 00	FY 01
Number Received	70	55	72	67	70
PMA Action					
Filing Decisions					
Filed	58	51	65	64	62
Not Filed	16	10	7	4	5
Others	0	0	0	0	0
Filing Decisions Subtotal	**74**	**61**	**72**	**68**	**67**
Scientific Review Decisions					
Major Deficiencies	38	28	32	51	35
Minor Deficiencies	5	10	4	11	4
Other[a]	138	105	105	111	95
Scientific Review Decisions Subtotals	**181**	**143**	**141**	**173**	**134**
Approval Decisions					
Approvals	48	46	45	43	53
Approvable	14	7	7	33	18
Not Approvable	5	12	1	4	10
Denials	0	0	0	0	0
Approved Decision Subtotal	**67**	**65**	**53**	**80**	**81**
Total PMA Actions	**322**	**269**	**266**	**321**	**282**
Average Review Time (Days) for Approvals[b]					
FDA	207	154	149	158	129
Non-FDA	40	37	26	40	43
Total	**247**	**191**	**175**	**198**	**172**
Average Elapsed Time (Days) for Approvals[c]					
FDA	375	265	280	244	257
Non-FDA	122	108	100	119	154
Total	**497**	**373**	**380**	**363**	**411**
Number under Review at End of Period[d]					
Active	44	29	49	35	45
(Active and Overdue)	0	0	0	0	0
On Hold	41	41	38	41	35
Total	**85**	**70**	**87**	**76**	**80**

***/** For FY 97, 98 and FY 99, PMA data includes a special category of PMAs. Humanitarian Devices Exemption (HDE) applications are similar in both form 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 abandoment or withdrawal of the PMA, placing the PMA on hold, and other miscellaneous administrative actions.

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

c/ The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus the average elpased 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 97 – FY 01

	FY97	FY98	FY99	FY00	FY01
Original PMAs Received					
PMAs	46	32	48	60	28
Expedited PMAs	10	6	7	8	4
Total	**56**	**38**	**55**	**68**	**32**
Filing Decisions [a]					
Filed	56	38	55	68	32
Not Filed	8	3	1	3	1
Number (%) of Filing/Not Filing Decisions within 45 Days	51(80)	30(73)	44(79)	54(76)	19(58)
Average Days/Cycle	39	44	42	40	45
Final Actions [b]					
Approvals	45	26	51	38	10
Denials	0	0	0	0	0
Other [c]	23	19	10	14	3
Total	**68**	**45**	**61**	**52**	**13**
Filing to First Action Excluding withdrawals, conversions, etc. [d]					
Number Received and Filed	56	38	55	68	32
Number of First Actions	53	37	55	63	32
Average FDA Days	147	134	145	132	133
Median FDA Days	175	145	147	143	155
Number (%) of First Actions with 180 Days	41(77)	32(87)	43(78)	63(100)	31(97)
Filing to First Action Including withdrawals, conversions, etc. [e]					
Number Received and Filed	56	38	55	68	32
Number of First Actions	56	38	55	68	32
Average FDA Days	146	134	145	133	133
Median FDA Days	173	141	147	136	155
Number (%) of First Actions with 180 Days	43(77)	33(87)	43(78)	68(100)	31(97)
Filing to Final Action Excluding withdrawals, conversions, etc. [f]					
Number Received and Filed	56	38	55	68	32
Number of Final Actions	45	28	48	41	10
Average FDA (Total) Elapsed Time	284(377)	238(348)	267(382)	210(293)	172(203)
Median FDA (Total) Elapsed Time	237(297)	198(220)	251(344)	180(252)	177(188)
Number (%) of Final Actions with 180 FDA Days	18(40)	12(43)	8(17)	21(51)	8(80)
Number (%) of Final Actions with 180 Total Days	15(33)	10(36)	5(10)	7(17)	5(50)
Filing to Final Action Including withdrawals, conversions , etc. [g]					
Number Received and Filed	56	38	55	68	32
Number of Final Actions	55	36	52	54	10
Average FDA (Total) Elapsed Time	269(413)	220(404)	268(392)	199(283)	172(203)
Median FDA (Total) Elapsed Time	207(339)	180(288)	252(356)	180(248)	177(188)
Number (%) of Final Actions with 180 FDA Days	23(42)	19(53)	9(17)	32(59)	8(80)
Number (%) of Final Actions with 180 Total Days	17(31)	11(31)	5(10)	12(22)	5(50)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc. [b]	1.8	1.7	2.0	1.5	1.2

(Continued on next page.)

Table 5. Original PMA Receipt Cohort Performance*
FY 97 – FY 01

(Continued from previous page.)

	FY97	FY98	FY99	FY00	FY01
Percentile FDA Days from Filing to First Action[d]					
25th	118	99	115	99	104
50th (Median)	175	145	147	143	155
75th	182	175	179	177	177
90th	217	192	227	180	179
Percentile FDA Days from Filing to First Action[e]					
25th	111	99	115	99	104
50th (Median)	173	141	147	136	155
75th	180	174	179	175	177
90th	199	181	227	179	179
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	175(178)	154(158)	254(252)	162(204)	163(177)
50th (Median)	237(297)	198(220)	251(344)	180(252)	177(188)
75th	416(545)	328(467)	322(491)	277(397)	179(212)
90th	443(708)	392(888)	404(637)	319(482)	215(266)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	165(178)	141(168)	204(254)	151(195)	163(177)
50th (Median)	207(339)	180(288)	252(356)	180(248)	177(188)
75th	390(548)	285(645)	326(501)	249(381)	179(212)
90th	443(766)	392(888)	392(637)	311(482)	215(266)
Number Pending as of 9/30/01					
Active	0	0	0	3	10
(Active and Overdue)	0	0	0	0	0
On Hold[h]	1	3	3	12	15
Total	**1**	**3**	**3**	**15**	**25**
Summary of PMA Receipt Cohort					
Approved	45	26	51	38	10
Denied	0	0	0	0	0
Withdrawn	11	10	4	10	3
Other	12	9	6	4	0
Under Review	0	0	0	3	10
On Hold[h]	1	3	3	12	15
Total	**69**	**48**	**64**	**67**	**38**

*** /** For each fiscal year, September 30, 2001 was used as the cutoff date. The FY01 cohort represents only receipts through March 31, 2001 (first 6 months of the fiscal year). The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus the average elapsed time is the average time taken to obtain approval of a PMA from its filing date until it receives final approval.

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Table 5. Original PMA Receipt Cohort Performance FY 97 – FY 01

(Continued from previous page.)

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

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

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

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

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

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

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

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

Table 6. PMA Supplement Decision Cohort Performance*
FY 97 - FY 01

	FY97	FY98	FY99	FY00	FY01
Number Received	409	513	556	545	641
PMA Supplement Actions					
Panel Track Filing Decisions [a]					
Filed	15	7	17	14	10
Not Filed	1	2	2	3	4
Other	0	0	0	0	0
Filing Decision Subtotal	**16**	**9**	**19**	**17**	**14**
Scientific Review Decisions					
Major Deficiencies	3	4	12	14	9
Minor Deficiencies	1	2	0	1	0
Other [b]	128	62	60	83	78
Scientific Review Decisions Subtotal	**132**	**68**	**72**	**98**	**87**
Approval Decisions					
Panel Track Approvals [c]	4	5	11	12	10
Nonpanel Track Approvals	397	416	426	462	432
Approvable	49	47	25	100	100
Not Approvable	76	63	62	58	52
Approval Decision Subtotal	**526**	**531**	**524**	**632**	**594**
Total PMA Supplement Actions	**674**	**608**	**615**	**747**	**695**
Average Review Time (Days) for Approvals [d]					
FDA	100	82	76	76	71
Non-FDA	12	25	16	18	26
Total	**112**	**107**	**92**	**94**	**97**
Average Elapsed Time (Days) for Approvals [e]					
FDA	120	109	92	95	78
Non-FDA	23	43	26	27	32
Total	**143**	**153**	**118**	**122**	**110**
Number Under Review at End of Period [f]					
Active [g]	110	139	158	98	152
(Active and Overdue)	0	0	0	0	(6)
On Hold [h]	80	57	70	84	94
Total	**190**	**196**	**228**	**182**	**246**

*** /** For FY 99, PMA data includes a special category of PMAs. Humanitarian Devices Exemption (HDE) applications are similar in both form 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 fo the supplement, the status of the supplement as a special (change being effected) or 30-day submission, and other miscellaneous administrative action.

(Continued on next page.)

Table 6. PMA Supplement Decision Cohort Performance*
FY 97 - FY 01

(Continued from previous page.)

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

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

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

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

g/ FDA responsible for processing application.

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

Table 7. PMA Supplement Receipt Cohort Performance*
FY 97 - FY 01

	FY97	FY98	FY99	FY00	FY01
PMA Supplements Received					
PMA Supplements	396	501	530	531	296
Expedited PMA Supplements	2	1	2	3	0
Panel Track PMA Supplements	6	9	11	10	6
Expedited Panel Track PMA Supplements	1	0	4	1	0
Total	**405**	**511**	**547**	**545**	**302**
PMA Supplement Final Actions[b]					
Approvals	365	421	440	412	195
Denials	0	0	0	0	0
Other[c]	34	81	85	97	59
Filing to First Action Excluding withdrawals, conversions, etc.[a,d]					
Number Received and Filed	398	502	532	534	296
Number of First Actions	389	482	513	517	281
Average FDA Days	89	81	72	63	7
Median FDA Days	71	57	36	37	48
Number (%) of First Actions within 180 Days	346(89)	436(91)	464(91)	505(98)	270(96)
Filing First Action Including withdrawals, conversions, etc.[e]					
Number Received and Filed	398	502	532	534	296
Number of First Actions	398	500	532	532	291
Average FDA Days	89	80	73	64	70
Median FDA Days	68	47	35	35	44
Number (%) of First Actions within 180 Days	353(89)	453(91)	481(90)	520(98)	280(96)
Filing to Final Action Excluding withdrawals, conversions, etc.[f]					
Number Received and Filed	398	502	532	534	296
Number of First Actions	363	455	486	485	243
Average FDA (Total) Review Days	103(125)	91(115)	75(102)	65(81)	65(72)
Median FDA (Total) Review Days	68(80)	46(65)	34(47)	32(40)	37(43)
Number (%) of Final Actions within 180 Days	304(84)	376(83)	424(87)	461(95)	235(97)
Number (%) of Final Actions within 180 Total Days	286(79)	352(77)	402(83)	437(90)	224(92)
Filing to Final Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	398	502	532	534	296
Number of First Actions	394	498	520	509	253
Average FDA (Total) Review Days	106(141)	94(129)	79(115)	67(85)	64(71)
Median FDA (Total) Review Days	72(93)	49(68)	36(51)	34(42)	37(43)
Number (%) of Final Actions within 180 Days	323(82)	411(83)	452(87)	484(95)	254(97)
Number (%) of Final Actions within 180 Total Days	296(75)	371(75)	420(81)	454(89)	234(93)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[b]	1.1	1.1	1.1	1.1	1.0

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Table 7. PMA Supplement Receipt Cohort Performance*
FY 97 - FY 01

(Continued from previous page.)

	FY97	FY98	FY99	FY00	FY01
Percentile FDA Days from Filing to First Action[d]					
25th	29	22	19	21	26
50th (Median)	71	57	36	37	48
75th	162	169	147	113	127
90th	182	183	189	176	180
Percentile FDA Days from Filing to First Action[e]					
25th	29	22	19	20	26
50th (Median)	68	47	35	35	44
75th	151	155	135	109	123
90th	181	180	180	168	175
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	30(35)	22(25)	18(24)	19(25)	25(27)
50th (Median)	68(80)	46(65)	34(47)	32(40)	37(43)
75th	155(177)	173(178)	132(152)	101(116)	101(116)
90th	206(287)	202(279)	189(232)	174(180)	166(177)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	32(36)	22(24)	19(25)	19(25)	25(25)
50th (Median)	72(93)	49(68)	36(51)	34(42)	37(42)
75th	169(180)	174(181)	140(163)	107(123)	99(123)
90th	210(347)	203(314)	190(254)	174(189)	166(189)
Number Pending as of 9/30/01					
Active	0	0	2	2	19
(Active and Overdue)	0	0	0	0	(4)
On Hold[h]	4	4	10	23	24
Total	**4**	**4**	**12**	**25**	**43**
Summary of PMA Supplement Receipt Cohort					
Approved	365	421	440	412	195
Denied	0	0	0	0	0
Withdrawn	26	30	32	20	11
Other	8	51	53	77	48
Under Review	0	0	2	2	19
On Hold[h]	4	4	10	23	24
Total	**403**	**506**	**537**	**534**	**297**

***/** For each fiscal year, September 30, 2001 was used as the cutoff date. The FY01 cohort represents only receipts through March 31, 2001 (first 6 months of the fiscal year). The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus the average elapsed time is the average time taken to obtain approval of a PMA from its filing date until it receives final approval. Panel Track Supplement times are quantified in Table 8.

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Table 7. PMA Supplement Receipt Cohort Performance*
FY 97 - FY 01

(Continued from previous page.)

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

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

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

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

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

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

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

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

Table 8. PMA Panel Track Supplement Receipt Cohort Performance*
FY97 – FY01

	FY97	FY98	FY99	FY00	FY01
PMA Panel Track Supplements Received					
Filing Decisions [a]					
Filed	6	9	15	11	6
Not Filed	1	1	0	1	0
Number of Filing/Not Filing Decisions within 45 Days	5	9	10	10	5
Average Days/Cycle	45	42	45	39	40
PMA Panel Track Supplement Final Actions [b]					
Approvals	5	9	13	6	3
Denials	0	0	0	0	0
Other [c]	2	2	3	2	1
Filing to First Action Excluding withdrawals, conversions, etc. [d]					
Number Received and Filed	7	9	15	11	6
Number of First Actions	7	9	15	11	5
Average FDA Days	165	116	134	119	130
Median FDA Days	180	106	162	135	153
Number (%) of First Actions within 180 Days	4(57)	7(78)	13(87)	10(91)	5(100)
Filing First Action Including withdrawals, conversions, etc. [e]					
Number Received and Filed	7	9	15	11	6
Number of First Actions	7	9	15	11	5
Average FDA Days	165	116	134	119	130
Median FDA Days	180	106	162	135	153
Number (%) of First Actions within 180 Days	4(57)	7(78)	13(87)	10(91)	5(100)
Filing to Final Action Excluding withdrawals, conversions, etc. [f]					
Number Received and Filed	5	8	12	6	2
Number of First Actions	5	8	12	6	2
Average FDA (Total) Review Days	446(703)	287(343)	255(285)	214(231)	208(226)
Median FDA (Total) Review Days	454(454)	237(269)	192(239)	214(248)	208(226)
Number (%) of Final Actions within 180 Days	0(0)	1(13)	5(42)	2(33)	1(50)
Number (%) of Final Actions within 180 Total Days	0(0)	0(0)	4(33)	2(33)	1(50)
Filing to Final Action Including withdrawals, conversions, etc. [g]					
Number Received and Filed	7	9	13	8	3
Number of First Actions	7	9	13	8	3
Average FDA (Total) Review Days	407(692)	275(374)	253(281)	235(277)	198(226)
Median FDA (Total) Review Days	454(454)	232(296)	199(235)	214(291)	179(226)
Number (%) of Final Actions within 180 Days	1(14)	2(22)	6(46)	3(38)	2(67)
Number (%) of Final Actions within 180 Total Days	0(0)	0(0)	4(31)	2(25)	1(33)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc. [b]	2.3	1.8	1.8	1.5	1.3

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Table 8. PMA Panel Track Supplement Receipt Cohort Performance* FY97 – FY01

(Continued from previous page.)

	FY97	FY98	FY99	FY00	FY01
Percentile FDA Days from Filing to First Action[d]					
25th	143	87	84	88	86
50th (Median)	180	106	162	135	153
75th	190	175	179	157	179
90th	196	227	185	175	---
Percentile FDA Days from Filing to First Action[e]					
25th	143	87	84	88	86
50th (Median)	180	106	162	135	153
75th	190	175	179	157	179
90th	196	227	185	175	---
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	190(209)	229(235)	178(179)	144(144)	168(168)
50th (Median)	454(454)	237(269)	192(239)	214(248)	208(226)
75th	641(925)	355(474)	373(373)	266(295)	248(283)
90th	760(1736)	484(560)	433(488)	313(313)	248(283)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	186(209)	227(237)	179(179)	140(177)	168(168)
50th (Median)	454(454)	232(296)	199(235)	214(291)	179(226)
75th	641(925)	261(484)	361(361)	290(317)	248(283)
90th	760(1736)	484(621)	433(488)	458(510)	248(283)
Number Pending as of 9/30/01					
Active	0	0	2	2	4
(Active and Overdue)	0	0	0	0	(1)
On Hold[h]	4	4	10	23	2
Total	**4**	**4**	**12**	**25**	**6**
Summary of PMA Supplement Receipt Cohort					
Approved	5	9	13	6	3
Denied	0	0	0	0	0
Withdrawn	2	1	3	2	1
Other	0	1	0	0	0
Under Review	0	0	1	1	4
On Hold[h]	0	0	3	3	2
Total	**7**	**11**	**20**	**12**	**10**

*** /** For each fiscal year, September 30, 2001 was used as the cutoff date. The FY01 cohort represents only receipts through March 31, 2001 (first 6 months of the fiscal year). The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus the average elapsed time is the average time taken to obtain approval of a PMA from its filing date until it receives final approval.

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Table 8. PMA Panel Track Supplement Receipt Cohort Performance* FY97 – FY01

(Continued from previous page.)

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

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

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

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

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

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

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

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

Table 9. HDE Submissions Received FY97 – FY01

TYPE OF SUBMISSION	NUMBER RECEIVED				
	FY97	FY98	FY99	FY00	FY01
Humanitarian Device Exemptions (HDEs)					
Original Applications	4	8	12	11	5
Amendments	10	32	55	56	62
Supplements	0	0	4	10	16
Amendments to Supplements	0	0	3	12	8
Reports for Original Applications	0	0	6	9	24
Reports for Supplements	0	0	0	0	0
HDE Subtotal	**14**	**40**	**80**	**98**	**115**

Table 10. Original HDE Decision Cohort Performance

FY97 – FY01

	FY 97	FY 98	FY 99	FY 00	FY 01
Number Received	4	8	12	11	5
HDE Action					
Filing Decisions					
Filed	2	9	10	8	6
Not Filed	0	1	1	4	1
Others[a]	0	1	1	0	0
Filing Decisions Subtotal	**2**	**11**	**12**	**12**	**7**
Scientific Review Decisions					
Major Deficiencies	0	0	6	7	7
Minor Deficiencies	1	1	0	3	6
Other[b]	0	0	4	6	2
Scientific Review Decisions Subtotals	**1**	**1**	**10**	**16**	**15**
Approval Decisions					
Approvals	2	4	6	6	4
Approvable	0	0	5	1	0
Not Approvable	0	0	0	0	0
Denials	0	0	0	0	0
Approved Decision Subtotal	**2**	**4**	**11**	**7**	**4**
Other Final Decisions[c]	0	2	4	1	4
Total HDE Actions	**5**	**18**	**37**	**36**	**30**
Filing to First Action[d]					
Number of First Actions	2	6	13	8	6
Average Number of FDA Days	68	139	87	61	42
Number of First Actions Within 75 Days	1	1	7	8	6
Average Elapsed Time (Days) for Approvals[c]					
FDA	108	152	113	112	143
Non-FDA	12	0	50	104	100
Total	**120**	**152**	**163**	**216**	**243**
Average Number of FDA Cycles from Receipt to Final Action[f]	1.0	1.2	1.2	1.3	1.9
Number under Review at End of Period					
Active	2	3	2	2	1
Active and Overdue	0	0	0	0	0
On Hold	0	1	8	8	6
Total	**2**	**4**	**10**	**10**	**7**

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, abandonment warning letter or conversions to another regulatory category.

(Continued on next page.)

Table 10. Original HDE Decision Cohort Performance
FY97 – FY01

(Continued from previous page.)

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

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

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

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

h/ The application is under review by FDA.

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

Table 11. HDE Supplement Decision Cohort Performance FY97 – FY01

	FY97	FY98	FY99	FY00	FY01
Number Received	0	0	4	10	16
HDE Supplement Actions					
Scientific Review Decisions					
Major Deficiencies	0	0	1	0	0
Minor Deficiencies	0	0	0	0	0
Other[a]	0	0	2	0	1
Scientific Review Decisions Subtotal	**0**	**0**	**3**	**0**	**1**
Approval Decisions					
Approvals	0	0	3	10	11
Approvable	0	0	1	0	0
Not Approvable	0	0	0	1	1
Denials	0	0	0	0	0
Approval Decision Subtotal	**0**	**0**	**4**	**11**	**12**
Other Final Decisions[b]	0	0	0	0	1
Total HDE Actions	**0**	**0**	**7**	**11**	**13**
Filing to First Action[c]					
Number of First Actions	0	0	4	10	12
Average Number of FDA Days	0	0	57	44	52
Number of First Actions within 75 Days	0	0	4	10	8
Average Elapsed Time (Days) for Approvals[d]					
FDA	0	0	70	43	46
Non-FDA	0	0	24	33	0
Total	**0**	**0**	**94**	**76**	**46**
Average Number of FDA Cycles from Receipt to Final Action[e]	0.0	0.0	1.3	1.0	1.0
Number Under Review at End of Period[f]					
Active[g]	0	0	0	0	4
(Active and Overdue)	0	0	0	0	0
On Hold[h]	0	0	1	1	1
Total	**0**	**0**	**1**	**1**	**5**

a/ Includes actons 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.

(Continued on next page.)

Table 11. HDE Supplement Decision Cohort Performance FY97 – FY01

(Continued from previous page.)

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

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

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

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

g/ The application is under review by FDA.

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

Table 12. Original IDEs
FY 97 - FY 01

	FY97	FY98	FY99	FY00	FY01
Number Received	297	322	304	311	284
Number of Decisions					
Approved	172	201	176	213	208
Not Approved	79	82	82	66	53
Other[a]	21	42	47	41	23
Total	**272**	**325**	**305**	**320**	**284**
Percent (%) of Approvals Made during First Review Cycle[b]	69	71	68	76	80
Average FDA Review Time (days)	29	27	27	28	28
Percent (%) of Decisions Made within 30 Days	100	100	99	99	100
Number under Review at End of Period[c]	32	29	28	19	18
Number Overdue at End of Period	0	0	0	0	0

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

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

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

Table 13. IDE Amendments
FY 97 - FY 01

	FY97	FY98	FY99	FY00	FY01
Amendments Received[a]	223	226	275	240	206
Decisions on Amendments					
Approved	101	94	97	107	73
Not Approved	25	36	42	34	39
Other[b]	94	95	129	110	95
Total	**220**	**225**	**268**	**251**	**207**
Average FDA Review Time (days)	18	19	18	19	18
Percent (%) of Decisions Made within 30 Days	100	100	100	100	99
Average Approval Time (days) for IDEs with Amendments					
FDA Time	61	55	57	70	59
Non-FDA Time	84	35	88	66	82
Total Time[c]	**145**	**90**	**145**	**136**	**141**
Number of Amendments per Approved IDE	1.8	1.4	1.6	2.3	1.7
Amendments under Review at End of Period[d]	12	13	19	9	8
Amendments Overdue at End of Period	0	0	0	0	0

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

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

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

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

Table 14. IDE Supplements
FY 97 - FY 01

	FY97	FY98	FY99	FY00	FY01
Number Received	3,776	4,277	4,127	4,388	4,811
Number of Decisions	3,777	4,209	4,224	4,335	4,803
Average FDA Review Time (days)	21	21	20	20	21
Percent (%) OF Decisions Made within 30 Days	100	100	100	100	100
Number under Review at End of Period[a]	216	284	187	239	247
Number Overdue at End of Period	0	0	0	0	0

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

Table 15. 510(k) Decision Cohort Performance
FY 97 - FY 01

	FY97	FY98	FY99	FY00	FY01
Number Originals Received	5,049	4,623	4,458	4,202	4,248
Number of Decisions					
Substantially Equivalent	4,405	3,824	3,652	3,567	3,428
Not Substantially Equivalent	57	65	66	52	46
Other[a]	693	1,340	875	778	676
Total	**5,155**	**5,229**	**4,593**	**4,397**	**4,150**
Percent (%) Not Substantially Equivalent[b]	1.3	1.7	1.8	1.4	1.3
Average Review Time (Days)					
FDA Time[c]	97	89	80	77	75
Total Time[d]	130	114	102	102	96
Median Review Time (Days)					
FDA Time[c]	81	81	71	68	68
Total Time[d]	85	83	76	72	72
Percent (%) of Decisions made within 90 Days, based on					
FDA Time (e)	95	97	99	100	100
Total Time[d]	58	59	66	66	69
Number under Review at End of Period[f]					
Active[g]	1,287	1,057	943	850	934
(Active and Overdue)	0	0	0	0	0
On Hold[h]	865	487	461	370	382
Total	**2,152**	**1,544**	**1,404**	**1,220**	**1,316**

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

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

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

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

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

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

g/ FDA responsible for processing notification.

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

Table 16. 510(k) Receipt Cohort Performance*
FY 97 - FY 01

	FY97	FY98	FY99	FY00	FY01
Number of 510(k)s Received[a]					
Traditional	5,059	4,528	3,985	3,471	2,392
Special	0	80	396	584	522
Abbreviated	0	21	85	149	137
Total Receipts	**5,059**	**4,629**	**4,466**	**4,204**	**3,051**
Actions on 510(k)s					
Substantially Equivalent	4,150	3,573	3,603	3,397	2,246
Not Substantially Equivalent (%)[b]	53(1.3)	70(1.9)	63(1.7)	40(1.2)	27(1.2)
Other[c]	856	986	798	718	340
Total Actions	**5,059**	**4,629**	**4,464**	**4,155**	**2,613**
Average Cumulative Days for 510(k) Decisions					
Excludes Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	91	82	81	73	65
Total Time from Receipt to Final Decision[e]	116	104	104	91	74
All Decisions Including Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	89	81	79	72	64
Total Time from Receipt to Final Decision[e]	134	118	114	99	75
Number of Decisions (%) with 90 Days, Based on:					
FDA Days from Receipt to First Action	4,968(98)	4,612(100)	4,453(100)	4,197(100)	3,047(100)
FDA Cumulative Days from Receipt to Final Decisions	3,558(70)	3,529(76)	3,372(76)	3,364(80)	2,264(74)
Total Cumulative Days from Receipt to Final Decisions[e]	3,025(60)	3,025(65)	2,938(66)	2,917(69)	2,074(68)
Average Number of FDA Cycles from Receipt to Final Action	1.5	1.4	1.4	1.4	1.3
Percentile FDA (Total) Days from Receipt to Final Action					
25th	51(57)	47(51)	41(45)	35(41)	32(36)
50th (Median)	80(86)	75(83)	71(78)	65(73)	71(77)
75th	106(175)	90(149)	90(147)	89(126)	96(145)
90th	172(312)	160(256)	160(263)	155(238)	N/A(N/A)
Number under Review as of 9/30/01					
Active	0	0	1	17	169
Active and Overdue	0	0	0	0	0
On Hold	0	0	1	32	269
Total	**0**	**0**	**2**	**49**	**438**
Summary of 510(k) Receipt Cohort					
Substantially Equivalent	4,150	3,573	3,603	3,397	2,246
Not Substantially Equivalent	53	70	63	40	27
Other	856	986	798	718	340
Under Review	0	0	1	17	169
On Hold	0	0	1	32	269
Total	**5,059**	**4,629**	**4,466**	**4,204**	**3,051**

(Continued on next page.)

Table 16. 510(k) Receipt Cohort Performance*
FY 97 – FY 01

(Continued from previous page.)

***/** For each fiscal year, September 30, 2001 was used as the cutoff date. The FY01 cohort represents only receipts through June 30, 2001 (first nine months of the fiscal year).

a/ Includes Third Party 510(k)s: FY97 = 14; FY98 = 18; FY99 = 32; FY00 = 47; FY01 = 70

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, delted due to lack of response 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 or 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) has been met, the Agency will declare the PDP complete.

Humanitarian Device Exemptions (HDEs)

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

PMA Supplements

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

Investigational Device Exemptions (IDEs)

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

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

IDE Amendments

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

IDE Supplements

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

Premarket Notifications (510(k))

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

Appendix B – ODE Publications

The following is a bibliography of articles and abstracts prepared by the ODE staff and published or presented during FY 2001.

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Rechen EJ. Third Party Review of 510(k)s. Medical Design and Manufacturing (MD&M) West Conference, Anaheim, CA, January 2001.

Rechen EJ. Third Party Review of 510(k)s. Medical Design and Manufacturing (MD&M) East Conference, New York City, NY, June 2001.

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Robinowitz M. FDA Perspective. National Glycohemoglobin Standardization Steering Committee, AACC, Chicago, IL, July 30, 2001.

Rosenthal AR. 4th Seymour Gostin Memorial Lecture at Southwestern Medical Center, University of Texas, Dallas, TX, September 8, 2001.

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Sacks W. Emerging Technologies for the Detection and Diagnosis of Breast Cancer. Centers for Disease Control, Atlanta, GA, September 6, 2001.

Sacks W. The Moving Target (Evaluation of Medical Devices in the Face of Ever Advancing Technology and Ever Improving Assessment Methods). Medical Imaging Perception Society Conference, Warrenton, VA, September 21, 2001.

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Shulman M. Implementation of the 510(k) Paradigm and Premarket Notification. Medical Design and Manufacturing (MD&M) Minneapolis, MN, October 2000.

Shulman M. Premarket Notification Overview. The Evolution of the 510(k). Medical Design and Manufacturing (MD&M) West Conference, Anaheim, CA, January 2001.

Shulman M. Premarket Notification Regulatory Review. AMDM In Vitro Diagnostics 510(k) Workshop, Rockville, MD, April 2001.

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Shulman M. 510(k) Submissions 101. AdvaMed, Washington, DC, July 2001.

Sliva CA. CLIA' 88 and Home Use Tests, Regulatory Affairs Professional Society, Washington, DC, July 30-31, 2001.

Sliva CA. Update on Clinical Laboratory Improvement Amendments, American Association for Clinical Chemistry Health Care Forum, Chicago, IL, August 1, 2001.

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Ticehurst J. Use of Rapid Hepatitis and Syphilis Tests in the Public Health Setting, US Centers for Disease Control & Prevention, Atlanta, GA, February 2, 2001.

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Witten C. Hot Topic Forum, ASPS, Los Angeles, CA, October 2000.

Witten C. Roles and Requirements in Planning and Conducting a Clinical Trial. AAOS Washington, DC, December 2000.

Zhou SY, Yue LQ, Ho C, Weininger S, and Gray G. Statistical Issues for Substantial Equivalence Determination of Pulse Oximeters, FDA Science Forum, Washington, DC, February 15-16, 2001.

APPENDIX B

Staff College Presenters and Faculty

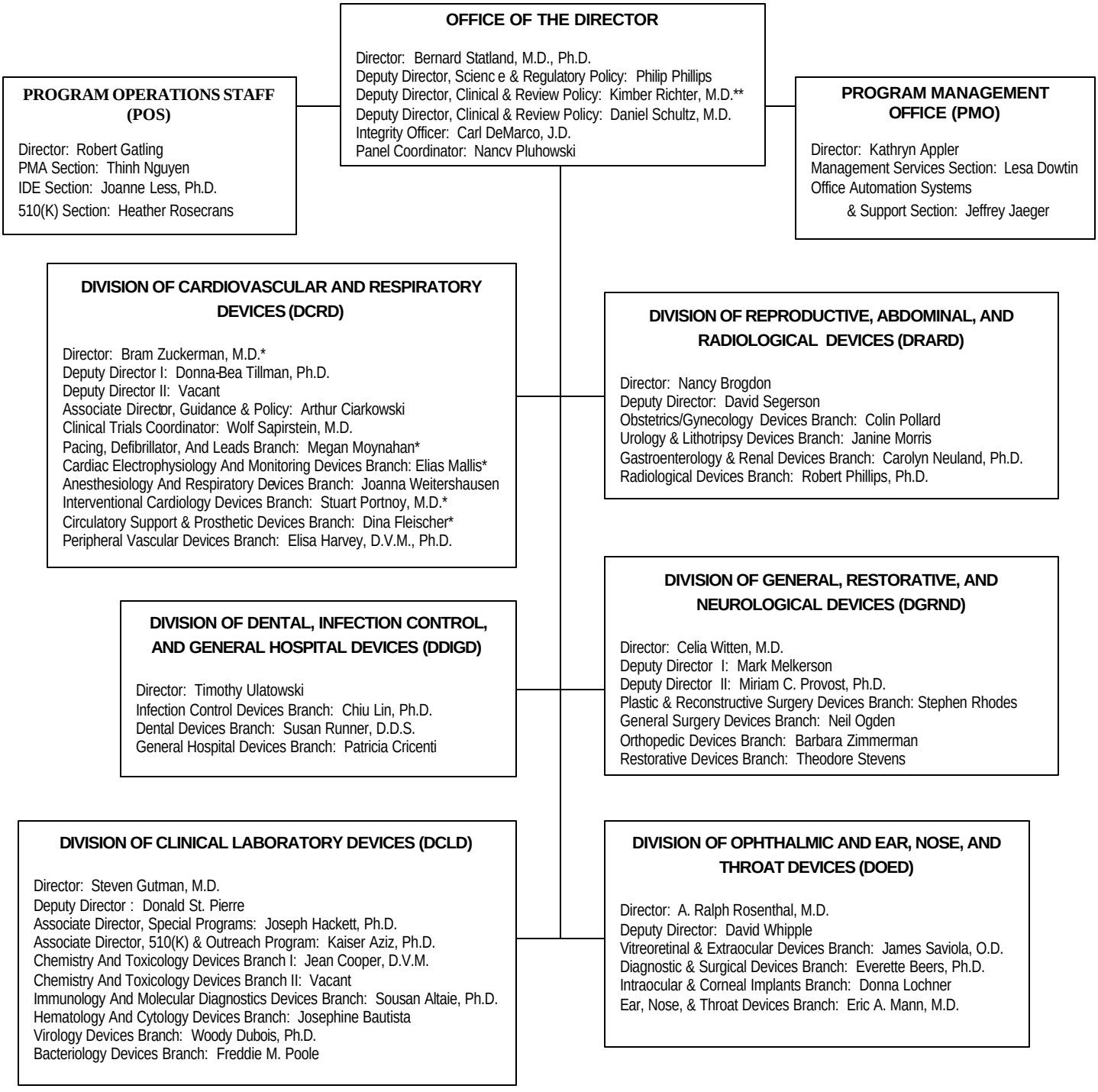
Abel, Dorothy
Allen, Peter
Aziz, Kaiser
Bazaral, Michael
Berman, Michael
Betz, Robert
Boam, Ashley
Brogdon, Nancy
Buckley, Donna
Cooper, Jean
Cygnarowicz, Teresa
DeMarco, Carl
Dillard, James
Eydelman, Malvina
Fuller, Janie
Gatling Jr., Robert
Gonzalea, Gema
Goode, Jennifer
Gutman, Steve
Harvey, Brian
Harvey, Elisa
Hawthorne, Cindy
Kammula, Raja
Kane, James
Karanian, John
Lappalainen, Sharon
Lemperle, Betty
Less, Joanne
Mayhall, Elaine
Melkerson, Mark
Meyers, Catherine
Mitchell, Diane
Morris, Janine
Moynahan, Megan
Neuland, Carolyn
Nguyen, Trinh
Ogden, Neil
Oktay, Hasan
Perticone, Diane
Phillips, Philip
Phillips, Robert
Pluhowski, Nancy
Pollard, Colin
Portnoy, Stuart
Rechen, Eric
Rhodes, Stephen
Robinowitz, Max
Romanell, Lawrence
Rosecrans, Heather
Sacks, William
Saperstein, Wolf
Segerson, David
Shein, Mitchell
Shulman, Marjorie
St. Pierre, Donald
Statland, Bernard
Tillman, Donna-Bea
Ulatowski, Tim
Witten, Celia
Wright, Kathleen
Zuckerman, Bram

Appendix C – Selected FDA Web Sites

Breast Implants: Consumer Information	http://www.fda.gov/cdrh/breastimplants/index.html
CDRH's Home Page	http://www.fda.gov/cdrh/index.html
Division of Small Manufacturers International and Consumer Assistance	http://www.fda.gov/cdrh/consumer/index.html
Federal Advisory Committee Act Database	http://www.facadatabase.gov/public.asp
FDA's Home Page	http://www.fda.gov
Guidance Documents	http://www.fda.gov/cdrh/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/forms_pubs_otherdocs/fpo_files/reference/rfsoc_99.pdf
Third Party	http:/www.fda.gov/cdrh/thirdparty

Appendix D – ODE Organization Chart

as of 1/28/02



*Acting
** On Detail to Office of Compliance

Appendix E - ODE Staff Roster

Office of the Director

Cooper, Brooksie
DeMarco, Carl
Gornick, MaryAnn
Hobbs, Cathy
Phillips, Philip
Pluhowski, Nancy
Richter, Kimber
Schultz, Dan
Statland, Bernard

Program Management Office

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

Program Operations Staff

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

Division of Clinical Laboratory Devices

Altaie, Sousan
Aziz, Kaiser
Bautista, Josephine
Benson, Carol
Bernhardt, Pat
Beverly, Patricia
Blagmon, Djuana
Brindza, Larry
Bucher, Betty
Callaghan, Jim
Calvin, Veronica
Carlos, Rufina
Chace, Nina
Chesler, Ruth
Clark-Stuart, Michelle
Cooper, Jean
Dada, Valerie
Danishefsky, Avis
Dubois, Woody
Fourcroy, Jean
Fugate, Kearby
Gaffey, Claudia
Gutierrez, Alberto
Gutman, Steve
Hackett, Joe
Hanna, Nancy
Hawthorne, C. Ann
Heyliger, Marian
Hoard, Renita
Hyde, John
Ingram, Jr., Kenneth
Jones, Doris
King, Lisa
Lyle, Dave
MacArthy, Philip

Magruder, Louise
Mansfield, Elizabeth
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
Shaikh, Farzana
Shively, Roxanne
Simms, Tom
Sliva, Clara
St. Pierre, Don
Summers, Peter
Ticehurst, John
Torres Cabassa, Angel
Tsai, Miin-Rong
Weeks, Susan
Wei, Tena
Whitaker, Kathleen
Wilbon, Tonya
Wood, Geretta
Wright, Kathy

Division of Cardiovascular and Respiratory Devices

Abel, Dorothy
Barold, Helen
Bazaral, Mike
Berman, Michael
Brown, Michele
Buckley, Donna
Callaghan, Jim
Carey, Carole
Chandeysson, Paul
Cheng, Jim
Ciarkowski, Art
Danielson, Judy
Demian, Cindy
Dillard, Jim
Donelson, Jan
Enyinna, Kachi
Ewing, Lesley
Fleischer, Dina
Foster, Elaine
Foy, Joni
Gabriel, Lynette
Gantt, Doyle
Gomez-Novoa, Carmelina
Goode, Jennifer
Harris, Lisa
Harvey, Elisa
Hayden, Brenda
Ho, Charles
Holden, John
Hottenstein, Omar
Huynh, Ann
Hwang, Shang
Hyde, John
Jensen, Nick
Jones, Edwena
Kaiser, Suzanne
Kennell, Lisa
Kroen, Marian
Kurtzman, Steve
Lacy, Frank
Lacy, Fred
Lee, James
Lemperle, Bette
Letzing, Bill
Lyle, Judy
Moynahan, Megan
Nell, Diane
Noe, William
Oktay, Semih
Omobo, Sola
O'Neill, Carroll
Pagano, Russ
Patel, Hina
Peters, Kimberly
Portnoy, Stuart
Provost, Miriam

Ramdat, Deb
Robey, Thomas
Roy, Joydeb
Ryan, Tara
Samadnejad, Sami
Sapirstein, Wolf
Shanker, Rhona
Shein, Mitchell
Sloan, Chris
Smallwood, Senora
Staschen, Carl-Michael
Stuhlmuller, John
Subramanian, Ramiah
Swain, Julie
Terry, Doris
Tillman, Donna-Bea
Usher, Wil
Vaughan, Carolyn
Weitershausen, Joanna
Wentz, Catherine
Wolanski, Nicole
Zuckerman, Bram

Division of Dental, Infection Control, and General Hospital Devices

Adjodha, Michael
Barrett, Sue
Betz, Robert
Bezabeh, 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
Gantt, Gail
Hibbard, Viola
Levchuck, John
Lin, Chiu
Marshall, Felicidad
Mayhall, Elaine
Mulry, Kevin
Nakayama, Von
Naveau, Irene
O'Connell, Linh
O'Lone, Martha
Robinson, Mary Jo
Runner, Susan
Samuels-Reid, Joy
Sauberman, Harry
Scott, Pam
Shipps, Gerald
Shire, Sandra
Smith, Gwendolyn
Soprey, Pandu
Sung, Pei
Turtil, Steve
Ulatowski, Tim

Division of General, Restorative, and Neurological Devices

Allen, Peter
Allen, Samie
Anderson, Jodi
Arepalli, Sam
Ashar, Binita
Basu, Sankar
Berkowitz, David
Bernato, Dolores
Berne, Bernard
Biddle, Timothy
Blair, Therian
Bourke, Tracey
Bowsher, Kristen
Buch, Barbara
Costello, Ann
Courtney, Mike
Dawisha, Sahar
DeLuca, Bob
Demian, Hany
Durfor, Charles
Einberg, Elmar

Eudy, Mike
Felten, Richard
Fogarty, Pauline
Foy, Keith
Gadaleta, Sergio
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
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
Zimmerman, Barbara

Division of Ophthalmic and Ear, Nose, and Throat Devices

Alexander, Kesia
Baker, Karen
Beers, Everette
Berman, Sheryl
Boam, Ashley
Brogdon, Nancy
Brown, Daniel
Burke-Nicholas, Marsha
Callaway, Jan
Calogero, Don
Chen, Tzeng
Cygnarowicz, Teresa
Drum, Bruce
Eydelman, Malvina
Falls, Deborah
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
McGhee, Eleanor
Montgomery, Al
Moore, Shirley
Ortega, Maritze
Romanell, Jake
Rorer, Eva
Rosenthal, Ralph
Saviola, James
Selfon, Eric
Shi, Dexiu
Shih, Ming-Chuen
Smith, Myra
Storer, Patricia
Thornton, Sara

Toy, Jeffrey
Trust Cohen, Linda
Warburton, Karen
Whipple, David

Division of Reproductive, Abdominal, and Radiological Devices

Appel, Sherrie
Arnaudo, Joe
Baxley, John
Bradley Allen, Cheryl
Brogdon, Nancy
Byrd, Laura
Chen, John
Cooper, Jeff
Cornelius, Mary Jo
Corrado, Julia
Czerska, Ewa
Dart, Linda
Daws-Kopp, Kathryn
Doyle, Bob
Eba, Felisa
Fredericksen, Jane
Gammell, Paul
Gonzalez, Gema
Harvey, Brian
Herrera, Hector
Howell, Kimberly
Jevtich, Milorad
Kammula, Raju
Kang, Andrew
Kuchinski, Mike
Lappalainen, Sharon
Lawrence, Lisa
Lutwak, Leo
Mackey, Cheryl
Mallis, Elias
McCool, Barbara
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
Whang, Joyce
Williams, Dick
Zaremba, Loren
Zaudtke, Peter
Yustein, Ron