OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 2002

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

Acknowledgements

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ODE Program Management Office
OSM Division of Planning, Analysis and Finance
OSM Division of Information Technology Management

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PREFACE

Dear Reader:

To say that we, in ODE, are living in an era of change is a major understatement. We are being asked to provide objective performance measures by way of scorecarding, move towards becoming an e-office, look 5 and 10 years down the road for strategic planning, design and manage a user fee program with outcome goals that are different and more challenging than any we have seen before, and look at ourselves as a part of the TPLC universe rather than the center of the premarket universe. And, as if these challenges aren't enough, we have the responsibility to do all of this with yet another new Director, and through it all not miss a beat when it comes to meeting our daily review quotas.

Based on past performance, I have no doubt that we will accomplish all this and more. Looking at the myriad of new technology evaluations, outreach programs, guidances, standards, and other initiatives documented in this report, I believe that what we have accomplished in the last twelve months is nothing short of astounding. I take it as a clear indication of what we will be capable of with additional resources and an effective plan to manage those resources.

I look forward to working with those of you within ODE, CDRH, and all of our many stakeholders to look at ways to communicate more effectively, improve our decision-making processes, and carry out our public health mission in a way that is fair, timely, and based upon the best available science.

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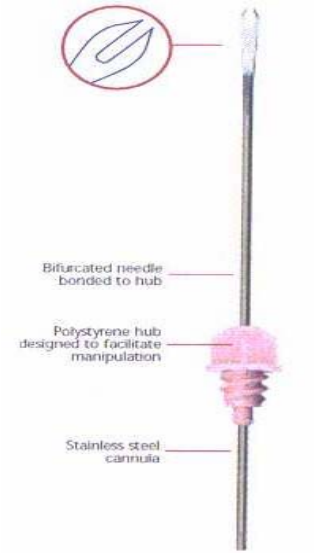
Part 1 – Advances in Patient Care

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. Below we highlight several new medical devices and devices with new indications approved or cleared during this past fiscal year that we believe will have a particular impact on patient care.

For a complete listing of newly approved devices, please see Part 2 – INDUSTRY INFORMATION under "Original PMA/HDE Approvals for Fiscal Year 2002." The Premarket Approval Application (PMA) approval website describing recently approved devices with patient information is available at http://www.fda.gov/cdrh/consumer/mda/index.html.

SMALLPOX VACCINE DELIVERY SYSTEM – The bifurcated needle has been developed specifically as a biodefense tool for the delivery of smallpox vaccine. The bifurcated needle is a specialized high quality two-prong needle that replaced jet injectors that had been used in the early years for conducting vaccinations. Its unique features make it the appropriate medical device for either large-scale immunization campaigns or emergency response. These thin metallic rods are approximately 50 – 70 mm long and 1 mm wide, with one end flattened and formed into two sharp tines. The u-shaped gap between the tines of the needle, when dipped into reconstituted smallpox vaccine, holds the vaccine by capillary action. The needle penetrates the stratum corneum layer of the skin and delivers a small amount of vaccine to the deep epidermis. The General Hospital Devices Branch has cleared three 510(k)s for bifurcated needles.

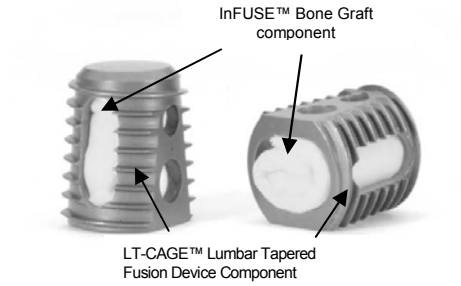


TUBERCULOSIS TEST – The QuantiFERON-TB from Cellestis Limited is the first *in vitro* test to detect cell-mediated immunity to Mycobacterium tuberculosis. The tuberculin skin test that has been used for over 50 years to detect cell-mediated immunity to M. tuberculosis is an *in vivo* test, requiring a repeat patient visit within 48-72 hours to read results. The QuantiFERON-TB assay on the other hand does not require a repeat visit to obtain results. It measures the release of IFN-g (gamma interferon) from lymphocytes in a whole blood sample during an overnight incubation with mycobacterial (PPD) and control antigens. It is indicated for testing individuals who originate from an area where tuberculosis is prevalent, or who are at increased risk by occupation or setting (e.g., healthcare workers, prisons, injection drug users). The assay is also indicated for testing population groups where the consequences of active infectious tuberculosis may be severe (military, healthcare workers, students at some institutions). Persons with a positive result may be at increased risk of subsequently developing active tuberculosis.

ADVANCES IN PATIENT CARE

GLUCOSE MONITORING WRIST WATCH FOR USE IN CHILDREN – The GlucoWatch G2 Biographer from Cygnus, Inc., is the first glucose monitoring device that doesn't puncture the skin that can be used by children, ages 7 and up, as well as adults. Diabetic children and adults wear the device like a watch where a slight electric current pulls glucose through the skin. Glucose levels are automatically read and recorded every 10 minutes for up to 13 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 measures glucose in interstitial fluid rather than in blood. Consequently, the GlucoWatch test results may sometime differ significantly from finger stick results. GlucoWatch does not replace finger stick testing.

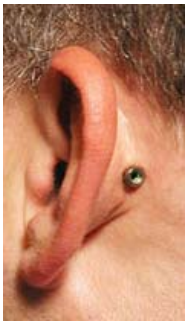
SPINAL FUSION DEVICE – InFUSE™ Bone Graft/LT-Cage™ Lumbar Tapered Fusion Device by Medtronic Sofamor Danek is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. The InFUSE™ Bone Graft/Lt -Cage™ Lumbar Tapered Fusion Device is a spinal fusion device that does not require the use of autograft, a bone taken from the patient's hip. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, function deficit and/or neurological deficit and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level. InFUSE™ Bone Graft/Lt-CAGE™ devices are to be implanted via an anterior open or an anterior laparoscopic approach. Patients receiving the InFUSE™ Bone Graft/Lt-Cage™ Lumbar Tapered Fusion Device should have had at least six months of nonoperative treatment prior to treatment with the InFUSE™ Bone Graft/Lt-Cage™ Device.

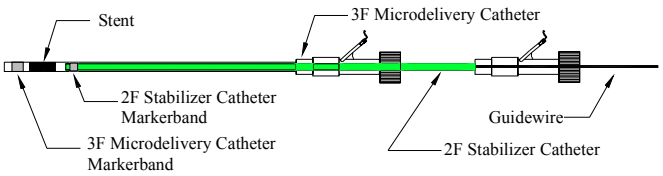


The device consists of three components spilt among two parts – [part 1] a metallic tapered spinal fusion cage (known as the LT-CAGE Lumbar Tapered Fusion Device); and [part 2] a bone graft substitute (InFUSE Bone Graft) which consists of a genetically-engineered human cytokine (rhBMP-2) and a carrier/scaffold for the cytokine (manufactured from bovine [cow] Type I collagen), that is placed inside of the fusion cage. The fusion cage component maintains the spacing and temporarily stabilizes the diseased region of the spine, while the InFUSE Bone Graft component is used to form bone which would permanently stabilize (fuse) this portion of the spine. The InFUSE Bone Graft component is used instead of the patient's own bone (autograft bone).

ADVANCES IN PATIENT CARE

HEARING AID – The RetroX Transcutaneous Air Conduction Hearing Aid System, manufactured by Auric Hearing Systems, Inc., is a new type of hearing aid that works without plugging the ear canal. This hearing aid sends sound through a tube that a doctor has inserted through soft tissue between the back of the outer ear and the outer ear canal. It is used anytime the user wants to improve hearing. It should not be used if there is local inflammation or infection in the skin behind the ear or if there is injury to the ear that would make placement of the tube impossible.





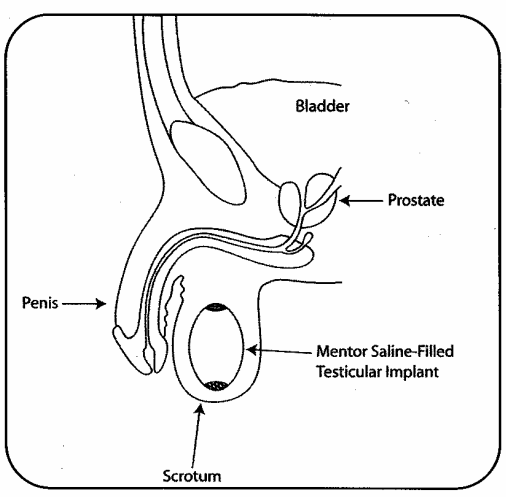
NEUROLOGICAL STENT FOR ANEURYSMS – Neuroform Microdelivery Stent by SMART Therapeutics, Inc. is intended for use with another medical device, embolic coils to treat patients with a certain kind of aneurysm in the brain who cannot be adequately treated by current surgical or endovascular techniques. The device consists of a self-expanding Nitinol mesh tube along with a microdelivery catheter. The stent is deployed across the neck of the aneurysm and embolic coils are placed through the struts of the stent into the aneurysm. The stent retains the embolic coils within the aneurysm, thus diverting the blood flow.

If left untreated or inadequately treated, wide neck aneurysms are at a high risk of rupture, resulting in a high risk of patient morbidity and mortality. The Neuroform™ Microdelivery Stent System is designed to address the limitations associated with the placement of coils in wide neck aneurysms.

NEUROLOGICAL STENT FOR RECURRENT INTRACRANIAL STROKE – NEUROLINK® System by Guidant Corporation is composed of a Stent Delivery Catheter and a Balloon Dilatation Catheter. The NEUROLINK® System is indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease. The device is a balloon expandable stainless steel mesh tube that is designed to open up the target blood vessel and provide structural support. The device is intended for patients who have $\geq$ 50% stenosis in the target intracranial vessels, leading to reduced blood flow to the brain with accompanying neurological symptoms. The Balloon Dilatation Catheter allows the physician to open up narrowed atherosclerotic areas in the blood vessel prior to placement with the stent. The NEUROLINK® System is the first device approved to treat these patients.

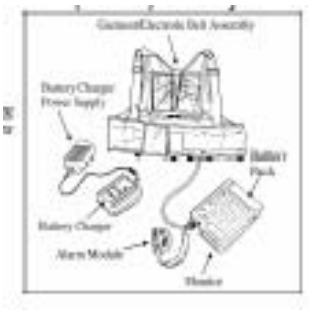
ADVANCES IN PATIENT CARE

TESTICULAR PROSTHESIS – The Mentor Saline-Filled Testicular Prosthesis, manufactured by Mentor Corporation, is an oval, silicone elastomer device that is designed to approximate the weight, shape, and softness of the normal testicle. This device is implanted in the scrotum in males who desire cosmetic replacement of a missing testicle, and consists of a silicone elastomer shell with an injection port and recessed suture tab. Although the implanted device looks and feels like a natural testicle, it does not have any other function. The Mentor Saline-Filled Testicular Prosthesis is manufactured in four sizes to accommodate juvenile to adult anatomies. The device is packaged empty, and filled with sterile saline at the time of implantation.



NEW TYPE OF DEFIBRILLATOR – The Contak CD CRT-D by Guidant Corporation is a new type of implantable cardioverter defibrillator (ICD) that also has the ability to deliver cardiac resynchronization therapy. The device, the first of its kind, can be used to treat symptoms of advanced heart failure in certain people who already need an ICD. The device combines an implantable cardioverter defibrillator with cardiac resynchronization therapy (CRT). The defibrillator component detects and treats life-threatening heart rhythms. The CRT component coordinates the beating of the left and right ventricles of the heart so that they work together more effectively to pump blood throughout the body. The device is intended to treat people who already need an implantable defibrillator, whose heart timing is off and who, despite taking heart failure medication, have symptoms of advanced heart failure, such as fatigue, shortness of breath and difficulty performing daily activities.

EXPANDABLE INDICATION OF DEFIBRILLATOR – A new use was approved for the Ventak automatic implantable cardiac defibrillator by Guidant Corporation so that it can now be used prophylactically in many people who have had a previous heart attack and an ejection fraction ≤ 30%. Ejection fraction is a measure of how efficiently the heart pumps blood. A level of 30% or less is an indication of impaired function that puts heart attack survivors at increased risk for sudden cardiac death. The expanded indication is based on results from the MADIT II trial. The trial showed that use of these devices reduced total mortality by 31% for heart attack survivors with compromised heart function.



WEARABLE DEFIBRILLATOR - The wearable cardioverter defibrillator (WCD®) by Lifecor, Inc. is used by adult patients 24 hours a day to monitor and treat dangerous, abnormally fast heart rhythms. These abnormal rhythms lead to a complete absence of heart beat (sudden cardiac arrest) and death (sudden cardiac death) if they are not treated. The WCD is a combination of two different devices. As a cardioverter, it uses low-energy electrical shocks to return an abnormally fast heart beat (ventricular tachycardia, or "VT") to a normal rhythm. As a defibrillator, it uses high-energy shocks to return a very fast, disordered heart beat (ventricular fibrillation, or "VF") to a normal rhythm. The Wearable Cardioverter Defibrillator (WCD) does the same job as an implantable cardioverter defibrillator (ICD). The difference is that the WCD is non-invasive, which means that it requires no surgery, implantation, or entry into the body. Instead, patients wear a vest-like garment that holds the WCD parts - a monitor, electrodes, and small "alarm module." The WCD is fully automatic and requires no patient action to deliver treatment - but the patient is able to prevent treatment if it is not needed. The WCD® device is worn if a patient is at risk of sudden cardiac arrest and an implantable defibrillator is not wanted or is not practical.

FDA Consumer Websites

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

Part 2 – Industry Information

ODE 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/consumer/mda.

During Fiscal Year 2002, no PDPs were completed, but ODE approved 41 PMAs and 6 HDEs. These are listed below. We recommend turning to the PMA approval website, which is available at http://www.fda.gov/cdrh/consumer/mda, for easy-to-understand one pagers for each PMA approved.

Original PMA/HDE Approvals for Fiscal Year 2002

		COMPANY	DEVICE
11-Oct-01	P010019	CIBA Vision Corporation	Focus® Night & Day™
12-Oct-01	P000030	CIBA Vision Corporation	Focus® Night & Day™
17-Oct-01	H010002	Stryker Biotech	OP-1™ Implant
02-Nov-01	P000052	Guidant Corp.	GALILEO™ Intravascular Radiotherapy System
09-Nov-01	P010007	Diagnostic Products Corporation	Immulite/Immulite 2000 AFP
16-Nov-01	P980033	Boston Scientific Scimed, Inc.	WALLSTENT® Venous Endoprosthesis with Unistep™ Plus RP Delivery System (10mm Venous Endoprothesis) WALLSTENT® Venous Endoprosthesis with Unistep™ Plus Delivery System (12mm-16mm Venous Endoprotheses)
16-Nov-01	P990015	Lifecore Biomedical, Inc.	Intergel (Adhesion Prevention Solution)
19-Nov-01	P000057	Ascension Orthopedics, Inc.	Ascension MCP
21-Nov-01	P010027	Ophthalmic Innovations Int'l Inc.	Allergan, Inc. Model AC21B Ultra
21-Nov-01	P010032	Advanced Neuromodulation System, Inc.	Genesis Neurostimulation (IPG) System
28-Nov-01	P010033	Cellestis Limited	QuantiFERON - TB
03-Dec-01	P010003	CryoLife, Inc.	Bioglue® Surgical Adhesive
05-Dec-01	P000039	AGA Medical Corporation	AMPLATZER® Septal Occluder (ASO) & the AMPLATZER® Exchange System
05-Dec-01	P000049	Nitinol Medical Technologies, Inc.	CardioSEAL® Septal Occlusion System with QuikLoad™
14-Dec-01	P010022	Cohesion Technologies, Inc.	CoSeal™ Surgical Sealant
18-Dec-01	P010020	American Medical Systems, Inc.	AMC Acticon Neosphincter (Fecal Incontinence Device)
18-Dec-01	P010030	Lifecore, Inc.	WCD® 2000 System
19-Dec-01	H000002	VISX, Inc.	VISX Custom Cornea Ablation Pattern
15-Jan-02	P000048	Dornier Medtech America, Inc.	Dornier Epos Ultra
15-Jan-02	P010038	Intelligent Systems Software, Inc.	Mammoreader (Computer-Aided Detection System)

31-Jan-02	P010034	CADx Medical Systems Inc. Parexel Intl. Corp	Second Look ™ (Computer-Aided Detection System for Mammography
28-Feb-02	P010054	Roche Diagnostics Corporation	Elecsys Anti-HBs Immunoassay
05-Mar-02	P990065	Sirtex Medical Limited Matrix Medical Consulting Corp.	Sir-Spheres (Radionuclide Microspheres)
14-Mar-02	P010043	Yama, Inc.	Lea's Shield Barrier Contraceptive
15-Mar-02	P010025	Hologic, Inc.	Lorad Digital Breast Imager (Full Field Digital System, X-Ray, Mammographic)
15-Mar-02	P010040	Safeguard Medical Devices, Inc.	The "Disintegrator" Insulin Needle Destruction Device
22-Mar-02	H010005	Ascension Orthopedics, Inc.	Ascension® PIP
25-Mar-02	P010049	SUB-Q, Inc.	QuickSeal™ Femoral Arterial Closure System
03-Apr-02	P000033	Sulzer IntraTherapeutics, Inc.	IntraCoil® Self-Expanding Peripheral Stent
05-Apr-02	H000007	AGA Medical Corporation	AMPLATZER® PFO Occluder
11-Apr-02	P010018	Refratec, Inc.	ViewPoint™ CK System
02-May-02	P010012	Guidant Corporation	CONTAK CD® CRT-D (Cardiac Resynchronization Therapy Defibrillator) System and EASYTRAK Coronary Venous Steroid-Eluding Single-Electrode Pace/Sense Lead, Models 4510, 4511, 4512, 4513
22-May-02	P010002	U.S. Surgical Corp.	Indermil™ Tissue Adhesive
13-Jun-02	P000028	Medtronic Sofamor Danek, Inc.	Affinity™ Cage System
24-Jun-02	P010041	Edwards Lifesciences, LLC	Carpentier-Edwards S.A.V. Bioprosthesis, Model 2650 (Aortic)
26-Jun-02	P010031	Medtronic, Inc.	Insync® ICD 7272 Dual Chamber Implantable Cardioverter Defibrillator with Cardiac Resynchronization Therapy and the Model 9969 Application Software
02-Jul-02	P000058	Medtronic Sofamor Danek, Inc.	Infuse Bone Graft/Lt-Cage Lumbar Tapered Fusion Device
19-Jul-02	P010039	Siemens Medical Solutions USA, Inc.	Siemens Sonocur Basic System
19-Jul-02	P020003	Mentor Corporation	Mentor Saline-Filled Testicular Prosthesis
22-Jul-02	P010052	Diagnostic Products Corporation	IMMULITE®/IMMULITE® 2000 Anti-HBs
24-Jul-02	P010051	Diagnostic Products Corporation	IMMULITE®/IMMULITE® 2000 Anti-HBc
26-Jul-02	P010050	Diagnostic Products Corporation	IMMULITE®/IMMULITE® 2000 HBsAG
26-Jul-02	P010053	Diagnostic Products Corporation	IMMULITE®/IMMULITE® 2000 Anti-HBcIgM
09-Aug-02	H010004	Guidant Corp.	NEUROLINK® System
09-Sep-02	H020002	SMART Therapeutics, Inc.	Neuroform™ Microdelivery Stent System

11-Sep-02	P020009	Boston Scientific Scimed, Inc.	Express™ and Express2™ Monorail and Over-the-Wire Coronary Stent Systems
27-Sep-02	P010068	Biosense Webster, Inc.	NaviStar/Celsius DS Diagnostic/Ablation Deflectable 8mmTip Catheter

Significant Medical Device Approvals

The following devices were approved via PMAs, PMA Supplements, and HDEs or cleared via 510(k)s or classified via the Automatic Evaluation of Class III Designation process during FY 02. 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.

- PMA/HDE Approved Devices

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

Univec Bifurcated Sliding Sheath Syringe, by Univee, Inc. (March 19, 2002)

BD Bifurcated Needle, by Becton, Dickerson, Inc. (March 20, 2002)

Division of Cardiovascular Devices (DCD)

Wearable Cardioverter Defibrillator (WCD®) 2000 System by Lifecore, Inc. (December 18, 2001)

IntraCoil® Self-Expanding Peripheral Stent by Sulzer IntraTherapeutics, Inc. (April 3, 2002)

CONTAK CD® CRT-D (Cardiac Resynchronization Therapy Defibrillator) System and EASYTRAK Coronary Venous Steroid-Eluding Single-Electrode Pace/Sense Lead by Guidant Corporation (May 2, 2002)

Insync® ICD 7272 Dual Chamber Implantable Cardioverter Defibrillator with Cardiac Resynchronization Therapy and the Model 9969 Application Software by Medtronic, Inc. (June 26, 2002)

Cordis PALMAZ® Balloon Expandable Stent (renal stent) by Cordis Corporation (July 10, 2002)

Ventak Prizm 2 VR/DR, Ventak Prizm VR/DR, Ventak Prizm VR/DR HE, Ventak Mini IV and Ventak Mini III HE by Guidant Corporation (July 18, 2002)

Division of Clinical Laboratory Devices (DCLD)

QuantiFERON-TB by Cellestis Limited (November 28, 2001)

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

Infuse Bone Graft/Lt-Cage Lumbar Tapered Fusion Device by Medtronic Sofamor Danek, Inc. (July 7, 2002)

Neurolink® System by Guidant Corp. (August 9, 2002)

Neuroform™ Microdelivery Stent System by Smart Therapeutics, Inc. (September 9, 2002)

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

Focus® Night & Day™ soft contact lens by CIBA Vision Corporation (October 11, 2001)

PureVison™ (balafilcon A) Visibility Tinted Contact Lens by Bausch and Lomb Vision Care (November 20, 2001)

Paragon CRT™ and Quadra RG™ Rigid Gas Permeable Contact Lenses for Refractive Therapy by Paragon Vision Sciences (June 13, 2002)

Menicon Z™ Rigid Gas Permeable Contact Lens (for up to 30 days of wear) by Menicon Co., Ltd. (July 12, 2002)

Division of Reproductive, Abdominal and Radiological Devices (DRARD)

Mentor Saline-Filled Testicular Prosthesis by Mentor Corporation (July 21, 2002)

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

DCLD

RIA Cocaine Assay by Psychemedics Corporation (November 6, 2001)

RIA Methamphetamine and MDMA Assay by Psychemedics Corporation (January 23, 2002)

RIA Phencyclidine Assay by Psychemedics Corporation (February 8, 2002)

QUANTA LITE IgG anti-CCP Assay by Inova Diagnostics, Inc. (April 29, 2002)

RIA Cannabinoid Assay by Psychemedics Corporation (May 3, 2002)

Accu-Chek Advantage Module by Roche Diagnostics (June 2, 2002)

Freestyle Tracker Diabetes Management System by ThersaSense, Inc. (June 2, 2002)

DIASTAT Anti-CCP Assay by Axis-Shield, Inc. (July 23, 2002)

QUANTA Lite SLA Assay by Inova Diagnostics, Inc. (July 30, 2002)

QUANTA Lite Actin Assay by Inova Diagnostics, Inc. (September 20, 2002)

Automated Cellular Imaging System (ACIS) for Estrogen and Progesterone Receptors by ChromaVision Medical Systems, Inc. (September 30, 2002)

DOED

Artificial Cornea by Argus Biomedical Pty Ltd. (August 29, 2002)

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, 2002)

ODE Guidance Documents

ODE issued 2 Blue Book Guidance Memoranda and 22 other guidance documents this Fiscal Year, 15 final and 9 draft, which are listed below. Of the 24 total in FY02, 15 are Special Controls guidance, 9 final and 6 draft. These guidance documents and other previously issued guidance documents are available on the World Wide Web (CDRH homepage: http://www.fda.gov/cdrh) which provides easy access to the latest information and operating policies and procedures. They may also be obtained from the Division of Small Manufacturers International and Consumer Assistance (DSMICA, HFZ-200). To contact DSMICA, call 800-638-2041 or 301-443-6597; fax 301-443-8818; Email dsma@cdrh.fda.gov or write to DSMICA (HFZ-200, Food and Drug

Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307.) Many guidance documents are also available through the CDRH Facts-On-Demand (faxback service at 800-899-0381 or 301-837-0111).

- Final Guidance Documents Adopted

ODE

Procedures for Handling Inquiries Regarding the Need for an Investigational Device Exemptions Application for Research Involving Medical Devices (Blue Book Guidance Memorandum #D01-1, October 26, 2001)

Fax & E-mail Communication with Industry about Premarket Files Under Review (Blue Book Guidance Memorandum #A02-01, March 1, 2002)

Updated 510(k) Sterility Review Guidance; Final Guidance for Industry and FDA (K90-1, August 30, 2002)

DCD

Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry (July 1, 2002)

DCLD

Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA (December 4, 2001)

Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA (September 16, 2002)

DAGID

Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA (October 5, 2001)

Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff (February 7, 2002)

Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA (July 17, 2002)

Regulatory Status of Disinfectants Used to Process Dialysate Delivery Systems and Water Purification Systems for Hemodialysis; Guidance for Industry and FDA (August 30, 2002)

DGRND

Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Guidance for Industry and FDA (April 30, 2002)

Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA (July 17, 2002)

DOED

Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA (April 29, 2002)

DRARD

Class II Special Controls Guidance Document; Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA (November 28, 2001)

Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Guidance for Industry (June 18, 2002)

- Draft Guidance Documents for Comment Purposes Only

Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Draft Guidance for Industry and FDA (February 7, 2002)

Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO2) and Oxygen (PcO2) Monitors; Draft Guidance for Industry and FDA (February 12, 2002)

Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Draft Guidance for Industry and FDA (February 20, 2002)

Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA (March 7, 2002)

Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA (April 5, 2002)

Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA (May 14, 2002)

Implantable Middle Ear Hearing Device; Draft Guidance For Industry and FDA (June 12, 2002)

Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers (August 14, 2002)

Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer dl-(2-Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA (September 6, 2002)

FDA Industry Website

At the end of FY 02, FDA launched a new portal page on its Website to make it easier for FDA-regulated companies to find information they need to comply with regulations. Featured links on the page include:

- Guidance documents,
- Inspection references,
- Information on imports,
- Warning letters and other FDA enforcement activities.

The portal also provides easy access to regulatory information from FDA's centers. Companies can use the portal to contact FDA with questions, submit comments online about proposed FDA regulations, or sign up to attend meetings for which registration is required.

The new portal is at http://www.fda.gov/oc/industry.

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 2002 (FY 02). Most of the data discussed below can be found in the tables below and in Part 7- 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 2002 with 354 employees. During the year, ODE lost 23 full-time employees (13 scientific reviewers, 8 medical officers and 2 clericals) through resignation, reassignment or retirement, and added 27 new employees (10 scientific reviewers, 2 medical officers, 5 clericals and 10 non-paid student interns and contractors).

Workload

During FY 02, ODE received 10,321 major submissions compared to 10,282 major submissions in FY 01. [See Table 1 for a breakdown of major submissions received.]

Table 1. Major Submissions Received
FY 92 – FY 02

TYPE OF SUBMISSION	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Original PMAs	65	40	43	39	44	66	48	64	67	71	48
PMA Supplements	606	395	372	499	415	409	517	557	546	641	644
Original IDEs	229	241	171	214	253	297	322	304	311	284	312
IDE Amendments	297	320	254	210	219	223	226	275	240	206	252
IDE Supplements	3,644	3,668	3,020	3,171	3,189	3,776	4,277	4,127	4,388	4,811	4,724
510(k)s	6,509	6,288	6,434	6,056	5,297	5,049	4,623	4,458	4,202	4,248	4,320
Original HDE	0	0	0	0	0	4	8	12	11	5	5
HDE Supplements	0	0	0	0	0	0	0	4	10	16	16
Total	**11,350**	**10,952**	**10,294**	**10,189**	**9,417**	**9,824**	**10,021**	**9,801**	**9,775**	**10,282**	**10,321**

On the decision side, ODE completed the processing of 10,237 major submissions, compared to 9,954 major submissions in FY 01. [See Table 2 for major submissions completed.]

Table 2. Major Submissions Completed
FY 92 - FY 02

TYPE OF SUBMISSION	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Original PMAs	12	24	26	27	43	48	40	37	42	53	41
PMA Supplements	394	354	385	435	462	401	421	440	474	442	532
Original IDEs	215	248	174	210	260	272	325	305	320	284	307
IDE Amendments	297	324	256	213	218	220	225	268	251	207	251
IDE Supplements	3,469	3,814	3,070	3,181	3,121	3,777	4,209	4,224	4,335	4,803	4,711
510(k)s	4,862	5,073	7,135	7,948	5,563	5,155	5,229	4,593	4,397	4,150	4,376
Original HDE	0	0	0	0	0	2	4	6	6	4	6
HDE Supplements	0	0	0	0	0	0	0	3	10	11	13
Total	**9,249**	**9,837**	**11,046**	**12,014**	**9,667**	**9,875**	**10,453**	**9,876**	**9,835**	**9,954**	**10,237**

Premarket Approval Applications (PMAs)

ODE received 48 original PMAs (23 less than the number received in FY 01). The total number of PMAs in inventory (active and on hold) at the end of this fiscal year decreased from 85 in FY 01 to 65. The number of active PMAs under review decreased at the end of FY 02 to 34 compared to 46 last year, and those on hold decreased from 39 in FY 01 to 31 in FY 02.

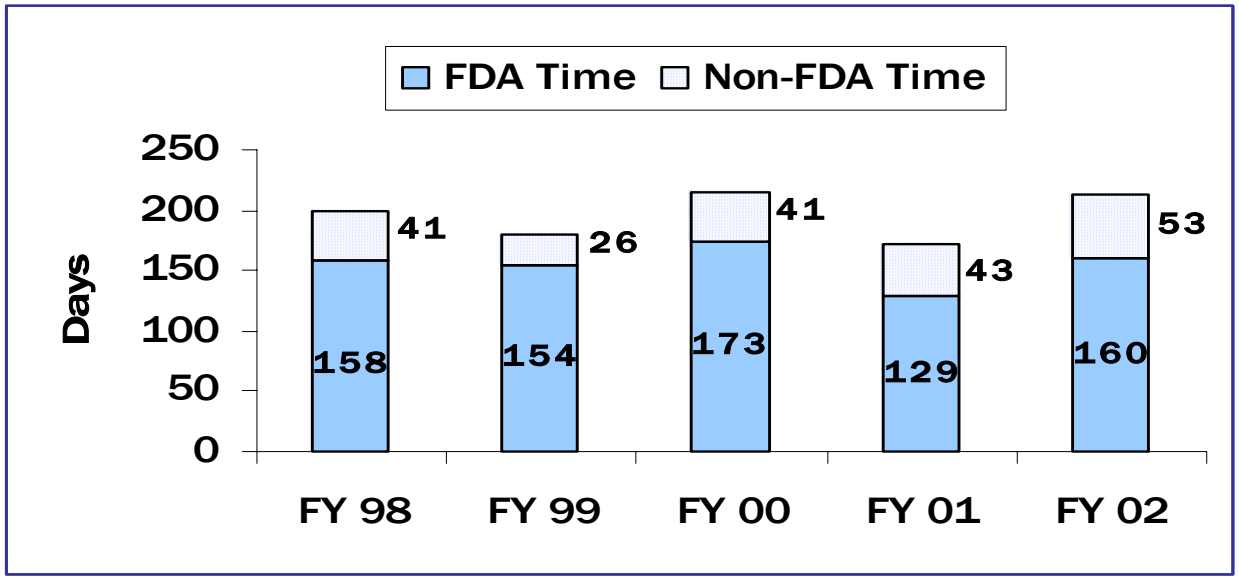
The total number of PMA actions decreased from 282 to 236 actions. These actions included 46 filing decisions, 122 review determinations, and 68 approval/approvable/not approvable decisions.

The 68 original PMA decisions were comprised of 41 approved PMAs, 17 approvable PMAs, and 10 not approvable PMAs. Of the 41 approvals, 10 were expedited PMAs. See Part 2 (INDUSTRY INFORMATION) for a complete list of PMA approvals.

Average FDA review time for original PMAs reaching approval increased from 129 days in FY 01 to 160 days in FY 02. The non-FDA component of review time increased from 43 days in FY 01 to 53 days this fiscal year. Thus, the total average review time increased to 213 days from 172 days.

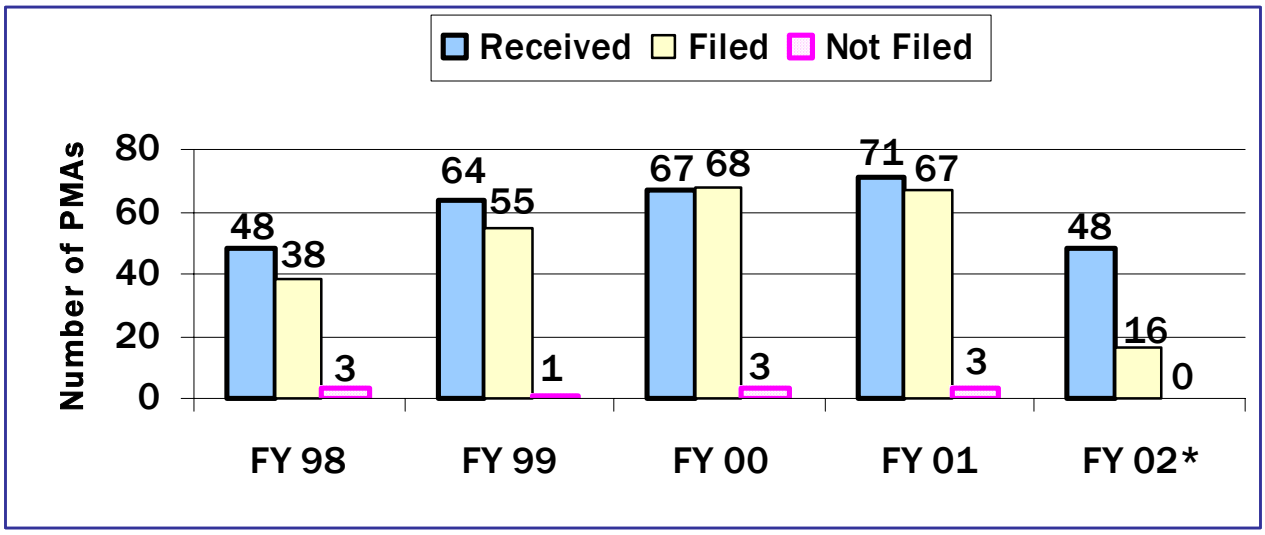
KEY PERFORMANCE INDICES

Figure 1. Average Review Time for PMA Decision Cohort Approvals



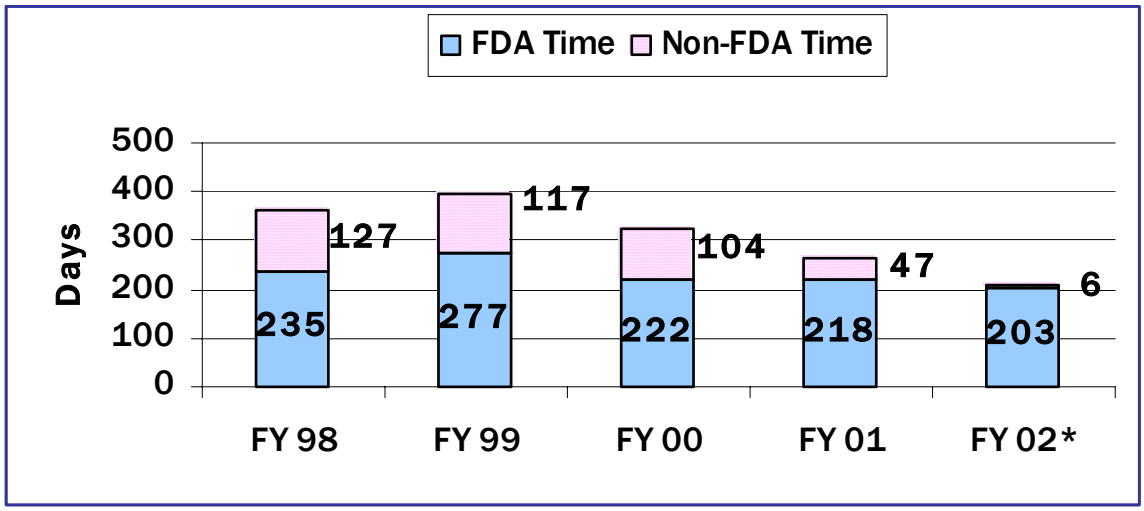
Of greater significance to industry is the total elapsed time from submission to decision. In FY 02, the total average elapsed time for PMA decision cohort performance decreased from 411 days in FY 01 to 364 days in FY 02.

Figure 2. Original Receipt Cohort PMAs Received and Filed



*First six months

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



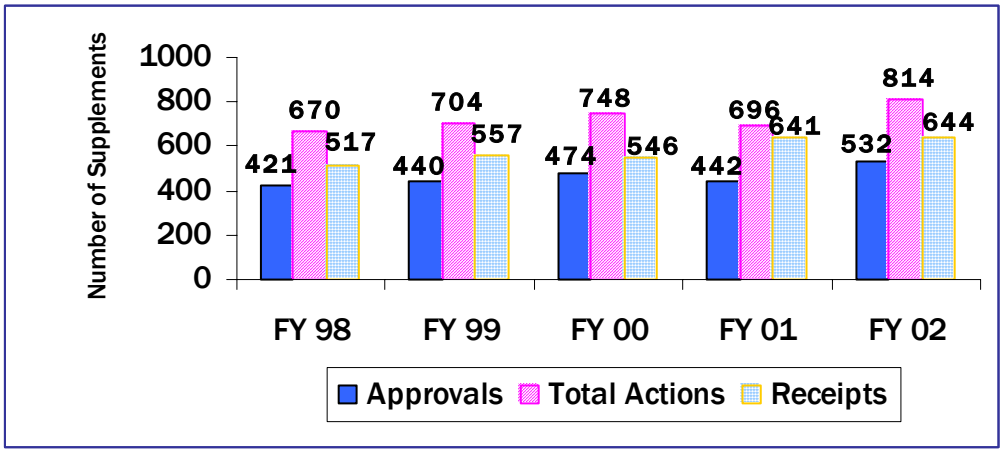
*First six months

For the first 6 months of FY 02 for PMA receipt cohort performance, the average FDA days from filing to first action decreased from 132 in FY 01 to 126 days.

The average FDA (total) elapsed time to an approval or to a denial decreased from 218(265) in FY 01 to 203(209) days in FY 02 (see Figure 3). The median FDA (total) elapsed time to an approval or denial decision decreased from 182(234) in FY 01 to 178(180) days in FY 02. This means that all of the statistics of the PMA receipt cohort for FY 02 indicate that we are making decisions faster.

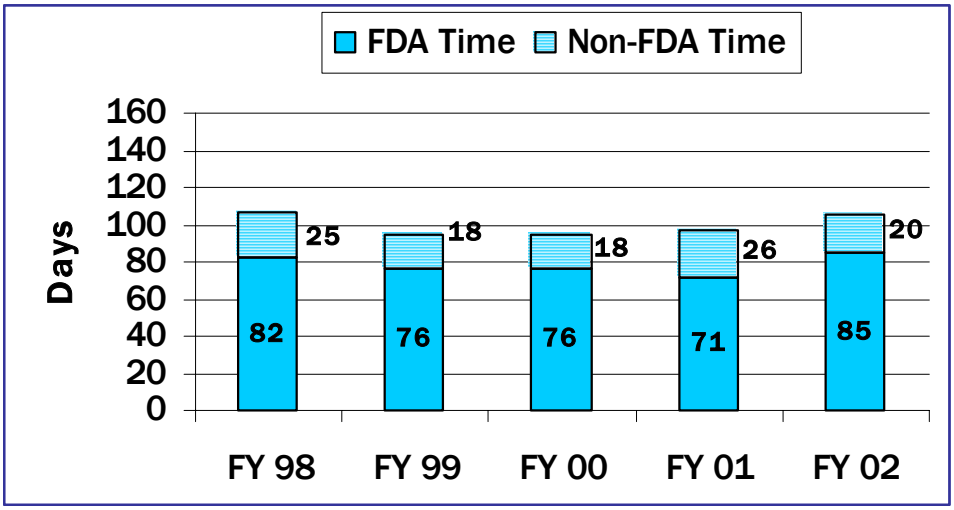
The number of PMA supplements received increased from FY 01's 641 to 644 in FY 02. There were 814 PMA supplement actions which is up from last year's 696 total actions. These actions included 24 panel track PMA supplement filing decisions, 105 scientific review decisions, and 685 approval decisions (see 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 97 days in FY 01 to 105 days in FY 02 (see Figure 5), and the average total elapsed time increased from 110 days to 124 days.

Figure 5. Average Review Time for PMA Supplements



Unlike in FY 98, FY 99, FY 00 and FY 01, there were no PMA supplements active and overdue at the end of this fiscal year. The number of active supplements decreased to 126 in FY 02 from 154 in FY 01, and the number of supplements on hold increased from 95 to 98. We received 3 more PMA supplements and are reaching final decisions on more, but we are taking an average of 14 more days for the decisions.

For the first 6 months of FY 02 for PMA supplements receipt cohort performance, the first action and final action are as follows. The average FDA days from filing to first action increased from 71 in FY 01 to 72 days in FY 02. The average FDA (total) elapsed time to an approval or denial decreased from 76(93) in FY 01 to 70(78) in FY 02. The median FDA (total) elapsed time to an approval or denial increased from 33(42) in FY 01 to 35(38) days in FY 02.

Real-Time Review of PMA Supplements

A total of 139 requests were received and processed for real time PMA supplements in FY 02 which represents 22% of all supplements received. Of those submissions, 117 were approved. Most applicants chose telephone conferencing versus a face-to-face meeting or a videoconference. The majority of these applications were reviewed in DCD (41%) followed by DGRND (24%), DOED (17%), DRARD (7%), DCLD (6%) and DAGID (5%). Overall, average review time from receipt to final approval was 38 days.

Product Development Protocols (PDPs)

No original PDPs were approved in FY 02. One routine PDP supplement and two "Real Time" 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 FY 02 ODE received a total of 30 PMA shells and 79 modules. A total of 11 modules were found to be acceptable while 11 received deficiency letters. A number of modules were rolled into PMA review during FY 02 because they were under review or on hold at the time the PMA was received. Applicants with modular submissions that were under review or deficient when the PMA was received continued to receive feedback under the PMA for those modules. However, this is based on a small number of submissions achieving PMA approval since modular review was implemented. A tracking system with modular PMA query capability became available during FY 99.

Humanitarian Device Exemption (HDE) Applications

ODE received 5 original HDEs, the same number received in FY 01. The total number of original HDE actions decreased from 30 in FY 01 to 23 in FY 02. These actions included 7 filing decisions, 8 review determinations, 6 approval decisions and 2 other final decisions.

A total of 6 first actions were made this fiscal year, equal to 6 made last year. The average time from filing to first action increased from 42 days in FY 01 to 53 days in FY 02.

Eighty-three percent of the first actions made in FY 02 occurred within 75 days.

The 6 approval decisions were comprised of 6 approved HDEs and no approvable HDEs.

In FY 02, the average elapsed time (from filing to final approval) for original HDEs was 302 days, an increase from 243 days in FY 01. The average FDA time was 175 days, an increase from 143 days in FY 01. The average non-FDA time was 127 days, an increase from 100 days last year.

The total number of original HDEs in inventory (active and on hold) at the end of this fiscal year was 4. Of these, 1 was under review and 3 were on hold. There were no active HDEs that were overdue at the end of the fiscal year.

The number of HDE supplements received stayed the same at 16 in FY 01 and 16 in FY 02. There were 27 HDE supplement actions in FY 02, up from 13 in FY 01. These actions included 13 approval, 6 approvable decisions and 6 not approvable decision.

A total of 17 first actions for HDE supplements were made this fiscal year, an increase from 12 last year. The average time from filing to first action increased from 52 days in FY 01 to 53 days in FY 02. Ninety-four percent of the first actions were made within 75 days.

The average elapsed time (from filing to final approval) for HDE supplements increased from 46 days in FY 01 to 74 days in FY 02. The average FDA time increased from 46 days in FY 01 to 60 days in FY 02. Non-FDA time increased from no days in FY 01 to 14 days in FY 02.

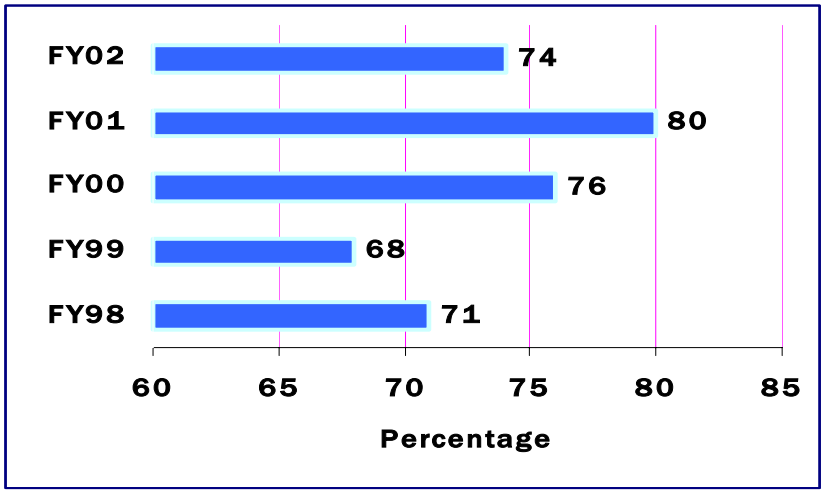
The number of HDE supplements in inventory (active and on hold) at the end of this fiscal year was 8. Of these, 4 were under review and 4 were on hold. There were no active HDE supplements that were overdue at the end of the fiscal year.

Investigational Device Exemptions (IDE)

During FY 02, ODE reviewed 297 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 312 original IDEs, an increase from 284 received in FY 01. There were 307 decisions made on original IDEs, an increase from 284 last year. Ninety-nine percent of all original IDE decisions were issued within 30 days in FY 02. 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 decreased from 80% in FY 01 to 74% in FY 02 (see Figure 6).

During this fiscal year, 252 IDE amendments were received. Decisions were made on 251 amendments: 86 approvals (34%); 55 disapprovals (22%); and 110 other administrative actions (44%). One hundred percent of these decisions were made within 30 days.

It took an average total time of 135 days to approve IDEs that were initially disapproved, down from 141 days in FY 01. This average approval time consisted of 68 days for FDA time, up from 59 days last year, and 67 days for non-FDA time, down from 82 days in FY 01.

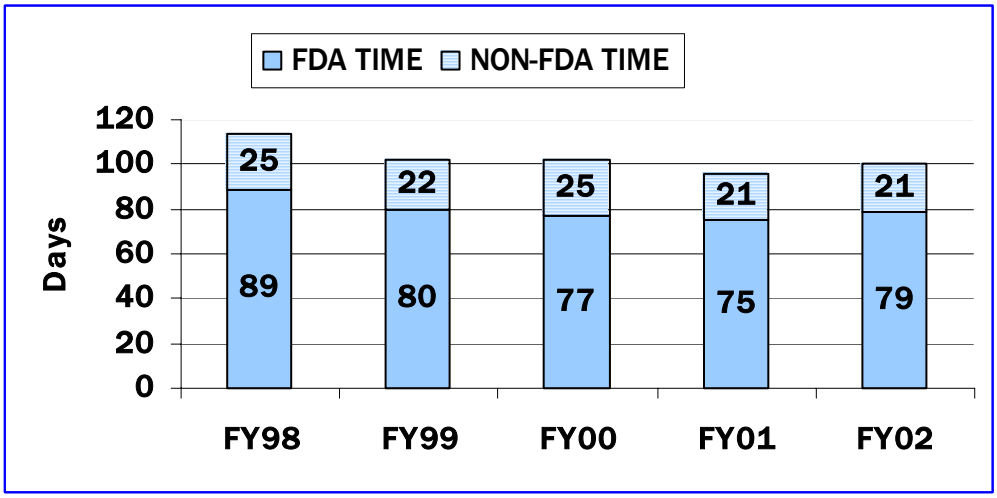
ODE received 4,724 IDE supplements during FY 02. There were no overdue supplements at the end of the year, and the percentage of supplements reviewed within the 30-day statutory timeframe was 100% in FY 02. The average review time for IDE supplements was 20 days, down from 21 days in FY 01.

Premarket Notification (510(k)s)

ODE received 4,320 original 510(k)s, as well as 1,780 510(k) supplements (responses to hold letters, the receipt of which restart the 90-day review clock), and 2,385 510(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 increased to 100 days in FY 02 from 96 in FY 01, and the average FDA review time was 79 days, up from 75 days in FY 01. 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 74 days in FY 02.

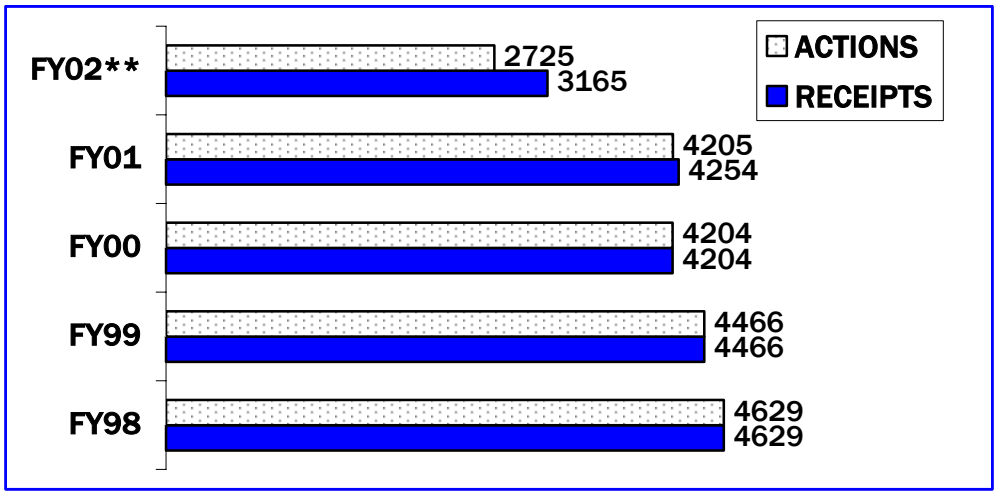
Figure 7. Average 510(k) Review Time for Decision Cohort



There were 1,272 510(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 02 was 337. Most important, for the seventh 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 02 for receipt cohort performance, the FDA time from receipt to final decision was 64 days.

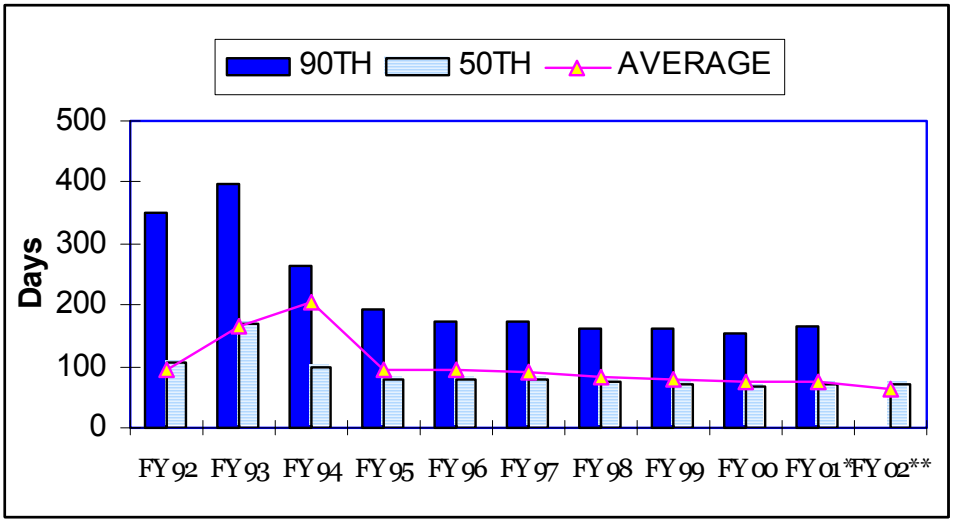
Figure 8. Receipts and Actions for 510(k) Receipt Cohorts*



*Cut Off Date of 9/30/02 for all receipt cohorts.
**12 month projection based on first 9 months of receipts.

For the first 9 months of FY 02 for receipt cohort performance, the total time from receipt to final decision increased to 76 days.

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



*Cut Off Date as of 9/30/02 for all receipt cohorts.
**For the first 9 months of FY 02. 90th percentile data not available for FY 02.

Third-Party Review of 510(k)s

During fiscal year (FY) 2002, ODE received 127 510(k)s reviewed by third-party organizations under the Accredited Persons provisions (section 523) of the Federal Food, Drug, and Cosmetic Act. This was a 19 percent increase over the 107 submissions received by ODE last fiscal year. The increase can be attributed to the expansion pilot implemented in March 2001 that permits third-party review of 510(k) submissions for a greatly expanded list of eligible 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. Submissions for expansion pilot devices increased from 8 in FY 2001 to 29 this year, while submissions for non-pilot devices remained virtually unchanged (99 in FY 2001 versus 98 this year).

ODE made final decisions on 132 "third party" 510(k)s in FY 2002, an increase from the 99 final decisions in FY 2001. 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 70 days for non-pilot devices and 105 days for expansion pilot devices, as compared to the average total elapsed time of 105 days (non-pilot devices) and 147 days (expansion pilot devices) for ODE's decisions on comparable 510(k)s that did not have a third-party review. Thus, 510(k)s with a third-party review received marketing clearance 33 percent faster (non-pilot devices) and 29 percent faster (expansion pilot devices) than comparable 510(k)s reviewed entirely by ODE.

Information on the 510(k) Accredited Persons Program and 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, 2001 to September 30, 2002 ODE received 787 *Special* 510(k)s out of the 4,320 total number of 510(k)s received, and 776 have received final decisions with the average FDA review time of 28 days and the average total time of 33 days, and 735 were found substantially equivalent, 2 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 185 *Abbreviated* 510(k)s out of the 4,320 total number of 510(k)s received. One hundred sixty-five received final decisions (131 substantially equivalent, 2 not substantially equivalent, and 32 other decisions) with a FDA average review time of 91 days and total time of 119 days. None of the *Abbreviated* 510(k)s went over 90 days.

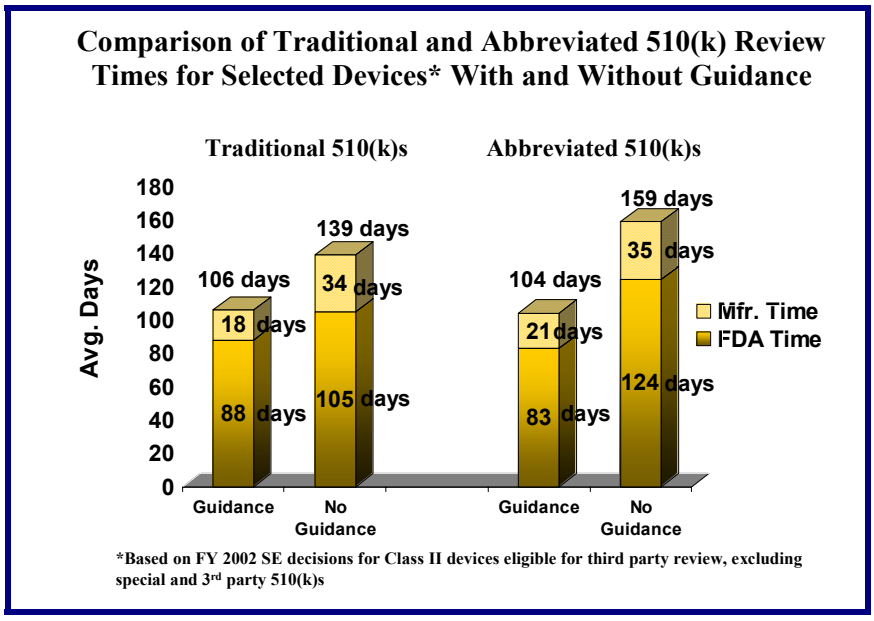
Device Guidance Documents

By the end of this fiscal year, ODE issued 15 final guidance documents and drafted for comment another 9 guidances. These documents are listed under Part 2 – Industry Information.

Guidance documents have become increasingly important in the review of PMAs and 510(k)s. In order to show the effect of guidance on 510(k) review times, we compared all SE decisions (1,644) for FY 2002 made on traditional and abbreviated 510(k)s for Class II devices eligible for third party review (excluding 510(k)s reviewed by 3rd parties). This analysis can only be conducted for class II devices eligible for third party review because the Center's classification database indicates whether guidance exists for these devices and not for others. These 1,644 decisions accounted for 58% of all SE decisions (2,808) made during FY 2002 for traditional and abbreviated 510(k)s that were not reviewed by 3rd parties. (The remaining 42% of traditional and abbreviated 510(k)s were for Class I devices, Class III devices, or Class II devices that are ineligible for 3rd party review because they are permanently implantable, life sustaining/supporting, or require clinical data.)

Specifically, the 1,644 510(k)s consist of 949 traditional 510(k)s and 72 abbreviated 510(k)s for devices with guidance and 603 traditional 510(k)s and 20 abbreviated 510(k)s for devices without guidance. Our analysis indicates that for these reviews, devices with guidance received marketing clearance 24% faster, on average, than devices without guidance (106 days versus 140 days).

The following chart illustrates the impact made by guidance documents on review times for 510(k)s.



Significant Medical Device Approvals

During FY 02, ODE approved 17 PMAs and cleared 13 510(k)s that represent significant medical device breakthroughs. See Part 2 - INDUSTRY INFORMATION, Significant Medical Device Approvals - for a complete listing.

Reclassification Petitions

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

Proposed Classification Actions

- Published a proposed rule in the *Federal Register* on February 7, 2002 to classify Resorbable Calcium Salt Bone Void Filler Device into class II.
- Published a proposed rule in the *Federal Register* on February 7, 2002 to classify Medical Washer and Medical Washer-Disinfector into class II.
- Published a proposed rule in the *Federal Register* on April 5, 2002 to classify Intraoral Devices for Snoring and/or Obstructive Sleep Apnea into class II.
- Published a proposed rule in the *Federal Register* on August 14, 2002 to classify Dental Sonography Device and the Jaw Tracking Device into class I and II (depending upon the indication).

Proposed Reclassification Actions

- Published a proposed rule in the *Federal Register* on February 12, 2002 to reclassify Cutaneous Carbon Dioxide (PcCO2) and the Cutaneous Oxygen (Pc)2) Monitor from class II (performance standards) to class II (special controls).
- Published a proposed rule in the *Federal Register* on February 21, 2002 to reclassify Cyclosporine and Tacrolimus Assays from class III to class II.

- Published a proposed rule in the *Federal Register* on May 14, 2002 to reclassify Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments from class III to class II.

Final Reclassification Actions

- Published a final rule in the *Federal Register* on November 15, 2001 to reclassify Three Anesthesiology Preamendments class III devices into class II. [Effective 12-17-01].

- Published a final rule in the *Federal Register* on January 14, 2002 to reclassify the Automated Differential Cell Counter from class III to class II. [Effective 2-13-02].

- Published a final rule in the *Federal Register* on April 29, 2002 to reclassify the Endolymphatic Shunt Tube with Valve from class III to class II. [Effective 5-29-02].

- Published a final rule in the *Federal Register* on April 30, 2002 to reclassify the Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis from class III to class II. [Effective 5-30-02]

- Published a final rule in the *Federal Register* on July 17, 2002 to reclassify Polymethylemthacrylate (PMMA) Bone Cement from class III to class II. [Effective 8-16-02]

- Published a final rule in the *Federal Register* on September 16, 2002 to reclassify Cyclosporine and Tacrolimus Assays from class III to class II. [Effective 10-16-02]

Automatic Evaluation of Class III Designation

- Issued an order on May 24, 2002 classifying the Air-Conduction Hearing Aid with a functional piercing (implanted portion) into class II.

Federal Register Notice

- Published a *Federal Register* Notice on September 6, 2002 Denying the Request for Change in Classification of Hip Joint Metal/Metal Semi-Constrained, With a Cemented Acetabular Component, Prosthesis and Hip Joint Metal/Metal Semi-Constrained, With an Uncemented Acetabular Component, Prosthesis from class III to class II.

Final 515(b) Call for PMAs

- Issued a final rule in the *Federal Register* on June 14, 2002 to require the filing of a Premarket Approval Application or Product Development Protocol for Glans Sheath Devices.

Part 4 – Major Program Initiative

Medical Device User Fee and Modernization Act of 2002

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), P.L. 107-250, amends the Federal Food, Drug, and Cosmetic Act to provide FDA important new responsibilities, resources, and challenges. FDA expended a great deal of effort in the preparation of MDUFMA during this fiscal year, and it was signed into law October 26, 2002. Negotiations began in the Spring 2002, and ODE and other Offices within CDRH worked with CBER, ORA, and the Office of the Commissioner, as well as our stakeholders, to make this legislation a reality. Key provisions include:

- User fees for premarket reviews, with significant performance goals to timeliness of reviews.
- Establishment inspections by accredited persons (third-parties).
- New regulatory requirements for reprocessed single-use devices.

More detailed information on the new law is available on CDRH Internet site http://www.fda.gov/cdrh/mdufma.

Part 5 – Other Program Activities

Guidance for Industry and Reviewers

In FY 02, ODE published 15 final guidance documents and published 9 draft guidance documents for comment. See INDUSTRY INFORMATION for a complete listing of all ODE guidance documents published in FY 02.

Least Burdensome

The two sections of the Food, Drug, and Cosmetic Act (the act) commonly referred to as the "least burdensome provisions" were enacted by Congress in 1997 to ensure the timely availability of safe and effective new products that will benefit the public and ensure that our Nation continues to lead the world in new product innovation and development. During the last few years, CDRH has been working with its stakeholders to develop an interpretation of the least burdensome provisions. In the May 3, 2001, Federal Register, the draft guidance document entitled, "The Least Burdensome Provision of the FDA Modernization Act of 1997: Concept and Principles" was released for comment. While the agency received very few comments on the draft, almost all of them strongly supported the guidance and encouraged full implementation of it as soon as possible. Several comments recommended that FDA develop a training program for its staff as well as ways to assess both the Agency's success in implementing the principles and the stakeholders' satisfaction with FDA's incorporation of them into its daily activities. The agency agreed with these recommendations and has incorporated them into the final guidance. The final document was released on the internet on September 30, 2002 and in the October 4, 2002 Federal Register (67 FR62252). The guidance may be found on the Center's website at www.fda.gov/cdrh/ode/guidance/1332.html.

Bioterrorism Preparedness

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

During this year, the Division of Clinical Laboratory Devices (DCLD) convened a classification panel to recommend classification of IVD products for the identification/detection of *B. anthracis* and *Y. pestis*. As a result of this panel, DCLD is developing notices of proposed rulemaking (NPRM) describing the proposed classification of these devices, and guidance containing the types of information needed to assess premarket submissions of the devices FDA is proposing to classify. DCLD is also working on the NPRM that proposes an amendment to the exception from general

requirements for informed consent to apply in certain circumstances when investigational IVDs are used to identify agents potentially associated with terrorism threats.

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

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

The Program Operations Staff (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, such as the NPRM discussed above.

Study Determination Inquiries

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

Often, the inquiries we receive can be easily answered by referring to the sources identified above. Occasionally, inquiries will present new situations not clearly identified in the regulation or the SR/NSR guidance. A few inquiries involve the scope of the IDE regulation and/or jurisdictional issues that may require consultation with the other FDA

centers. An IDE Memorandum (#D01-1) dated, October 26, 2001 was issued to establish written procedures for handling inquiries regarding the need for an IDE application for research involving medical device.

When responding to these inquiries, there are three possible responses: the research is exempt from the IDE regulation; the abbreviated IDE requirements must be met (nonsignificant risk [NSR] study); or the full requirements of the IDE regulation must be met, that is, an IDE application must be submitted to FDA (significant risk [SR] study). In FY 02 ODE received 76 inquires. Of the 76 inquires, there were 19 SR determinations, 33 NSR determinations, 19 exempt determinations, and 5 inquires still under review.

Significant Jurisdictional Issues

Title 21 of the Code of Federal Regulations Part 3 - PRODUCT JURISDICTION describes the procedure the agency uses to assign Center jurisdiction over medical products whose jurisdiction is not clear or is in dispute. Requests for Designations (RFDs) over such products are made in writing to the Office of 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 2002 CDRH participated in the review of 33 out of 37 (four 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 5 RFDs received in FY 2000. The reviews of the 33 new requests were assigned to the ODE Divisions as follows: DGRND was assigned 9 (nine); DAGID was assigned 8 (eight) to review and shared in the review of 2 others; DCD was assigned to review 5 (five); DRARD was assigned 4 (four) and shared in the review of one other; DOED was assigned 3 (three); and, DCLD was assigned 1 (one) and shared review in an one other. One RFD was not assigned to a division, rather it was handled by the Jurisdiction Coordinator.

Of the 33 FY 2002 RFDs in which CDRH was involved: CDRH was assigned the lead center in 13 (thirteen) of those requests; CDER was assigned lead center in 9 (nine); CBER was designated lead in 4 (four) RFDs; 2 (two) were withdrawn before their review could be completed; and, 5 (five) were not due for completion until FY2003.

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 FY02 DCLD performed categorizations on 231 High, 1564 Moderate, and 315 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 provides 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 02, ODE held 14 panel meetings. The panels reviewed and made recommendations on: 11 PMAs, 2 PMA supplements, 1 510(k), 1 reclassification petition, and 4 general issues. The panels reviewed significant medical device breakthrough technologies such as a spinal fusion cage with a growth factor soaked in a collagen sponge intended for use to treat lumbar degenerative disease, an implantable pacemaker/defibrillator used for treatment of both congestive heart failure and life threatening dysrhythmias, and a contact lens for corneal refractive therapy with overnight wear for the temporary reduction of myopia.

CDRH conducts training sessions for new panel members and consultants prior to their participation on a panel. In FY02, there were 13 training sessions for new members.

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/panel/index.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 47 cases concerning the integrity of data submitted to the agency in premarket applications. Under the Application Integrity Program (AIP), two firms were placed on the AIP list and AIP restrictions applied against this firm. An Integrity Hold was placed on one firm's application and removed from another firm's application during the fiscal year.

ODE handled 25 instances related to questions arising under the standards of conduct for employees. During FY 02, 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.

Part 6 - Program Support

Freedom of Information Requests

ODE staff received 739 FOI requests during FY 02, a decrease from 868 in the last fiscal year. During FY 02, the number of FOI requests closed was 1,141 compared to 1,048 in FY 01. The total number of FOI requests pending in ODE at the end of FY 02 is 345 compared to 420 in FY 01.

Congressional Inquiries

ODE staff responded to inquiries and participated in briefings on such topics as single use devices, breast implants, Medicare/Medicaid coverage issues, plano contact lens, on-site drug testing, CLIA, potassium iodide, biomedical life systems, electromagnetic devices, electrical stimulation devices, low frequency radiation, and tooth preparation instruments. ODE also participated in Congressional hearings held during FY02 dealing with FDA's budget, reuse of medical devices labeled for single use, and user fees.

Publications

During FY 02, ODE staff authored 9 manuscripts for publication in professional and scientific journals and delivered 88 presentations at professional, scientific and trade association meetings. See Appendix B for a bibliography of publications.

ODE Vendor Day

In FY 02, ODE, in conjunction with the Association of Medical Diagnostics Manufacturers (AMDM) sponsored a Vendor Day. This was an informative exhibit and exchange seminar with two device manufacturers of *Diagnostic and Safety Devices* comprised from four different groups to show different device areas: Diagnostics Systems, Injection and Infusion Therapy Business – safety products, Preanalytical Solutions – safety blood collection devices, and Biosciences. The Vendor Day was very successful with attendance from over 100 FDA employees.

Site Visits

In FY 2002, ODE continued its Site Visit Program that was developed in 1993 to enhance reviewer knowledge of how specific medical devices are designed, manufactured, and tested. The program continued to include not only visits to medical device manufacturing firms but also to hospitals for the observation of certain devices in use. Twenty-three firms and/or hospitals were visited by 156 scientific reviewers to learn about such things

as 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 a new employee with a mentor who is expected to provide technical, informational and career guidance to the employee in an effort to enable employee assimilation into the workforce and to ensure appropriate employee development. The ODE PMO Office has served as an informal mentoring agent for minorities.

Recruitment

To enhance the Center effort in the hiring of minorities and those with a disability, ODE participated in the 2002 Excellence in Government Conference; HHS Department Recruitment Fair; and the Department's Emerging Leaders Program.

ODE continues to increase its use of a variety of methods to improve its resources. In FY 2002, they included:

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

Training

ODE employees attended many courses, lectures, and grand rounds sponsored by the CDRH Staff College. They also attended local colleges and various off-site training institutions, and availed themselves of a multitude of other training opportunities associated with their field of expertise (e.g., meetings, seminars, workshops). ODE employees averaged 108 hours of training per employee in 2002. Supervisors continued to participate in monthly meetings to discuss current management issues, and all employees attended all-hands meetings to learn about new program polices and procedures.

Computer Tracking Systems

ODE tracking system changes included premarket database enhancements, revised report and query programs, and modifications to the division-level tracking system. One enhancement involved a field that was added to the division tracking system to capture the receipt of an electronic submission and to enable the consistent reporting of electronic submissions. Programming commenced on the effort to insert a field in the tracking systems to record the submission of applications representing a combination product. The reporting capability was greatly enhanced by automating the data compilation effort needed to prepare the ODE annual report.

Office Automation

During Fiscal Year 2002 ODE supported a number of software installations on its desktop PCs to provide a more current operating environment. Hardware improvements continued with the purchase of PCs and laptops and with the installation of Blackberry wireless handheld devices for senior management and individuals involved in special support activities. ODE reviewers helped to test and provide comments on the new document archival system (Image2000) which is slated to replace the original Image system initially developed in 1989. The ODE Intranet homepage was developed to serve as a portal to information needed by ODE employees.

Electronic Submissions

In Fiscal Year 2002, ODE received 73 complete electronic submissions for PMAs, IDEs, and 510(k)s from 14 different sponsors. These numbers show a steep decline from FY01 because ODE revised its definition of an electronic submission for Fiscal Year 2002 to indicate that the entire submission arrive at ODE in an electronic format. ODE plans to expand its electronic submission effort in FY03 and will share its plans with the regulated industry. Prior contact with an ODE division is still 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

ODE has the ability to conduct 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 2002, 5 video conferences were held involving industry and other Federal agencies.

Medical Device Web Home Page

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 on the CDRH home page under Device Program Areas/Device Evaluation Information. Information about new medical device approvals can be found on the device evaluation home page http://www.fda.gov/cdrh/ode/index.html. This page was redesigned in FY02 to consolidate links to information and to simplify the search for device-related information.

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/consumer/mda/index.html#databases.

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

Part 7 – Operational 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. For example, if an incoming PMA supplement is later converted to an original PMA, changes are made in the appropriate tables. Likewise, some data from earlier reporting periods may have been changed to reflect similar corrections in data entry. These adjustments are not likely to have a significant effect on conclusions based on these data. Percentages of actions are presented in some tables. They may not add up to 100% in all cases due to the rounding off of fractions.] Refer to Tables 1 (page 14) and 2 (page 15) for general summary of major submissions received and completed.

Table 3. PMA/HDE/IDE/510(k) Submissions Received FY 98 - FY 02

TYPE OF SUBMISSION	NUMBER RECEIVED				
	FY98	FY99	FY00	FY01	FY02
Premarket Approval (PMAs)					
Original Applications	48	64	67	71	48
Amendments	735	743	975	753	758
Supplements	517	557	546	641	644
Amendments to Supplements	863	954	933	919	864
Reports for Original Applications	430	423	420	492	583
Reports for Supplements	0	0	0	0	0
Master Files	95	69	45	37	44
PMA Subtotal	**2,688**	**2,810**	**2,986**	**2,913**	**2,941**
Humanitarian Device Exemptions (HDEs)					
Original Applications	8	12	11	5	5
Amendments	32	55	56	62	53
Supplements	0	4	10	16	16
Amendments to Supplements	0	3	12	8	20
Reports for Original Applications	0	6	9	24	29
Reports for Supplements	0	0	0	0	0
HDE Subtotal	**40**	**80**	**98**	**115**	**93**
Investigational Device Exemptions (IDEs)					
Original Applications	322	304	311	284	312
Amendments	226	275	240	206	252
Supplements	4,277	4,127	4,388	4,811	4,724
IDE Subtotal	**4,825**	**4,706**	**4,939**	**5,301**	**5,288**
Premarket Notification (510(k)s)					
Original Notifications	4,623	4,458	4,202	4,248	4,320
Supplements	2,023	1,872	1,742	1,579	1,780
Amendments	3,692	2,962	2,953	2,620	2,385
510(k) Subtotal	**10,338**	**9,292**	**8,897**	**8,447**	**8,485**
PMA/HDE/IDE/510(k) Total	**17,861**	**16,812**	**16,919**	**16,773**	**16,807**

Table 4. Original PMA Decision Cohort Performance FY 98- FY 02

	FY 98	FY 99	FY 00	FY 01	FY 02
Number Received	48	64	67	71	48
PMA Action					
Filing Decisions					
Filed	42	55	64	62	43
Not Filed	10	6	4	5	3
Others	0	0	0	0	0
Filing Decisions Subtotal	**52**	**61**	**68**	**67**	**46**
Scientific Review Decisions					
Major Deficiencies	28	27	51	35	29
Minor Deficiencies	9	4	11	4	2
Other[a]	130	126	111	95	91
Scientific Review Decisions Subtotal	**167**	**157**	**173**	**134**	**122**
Approval Decisions					
Approvals	40	37	42	53	41
Approvable	9	10	33	18	17
Not Approvable	12	1	4	10	10
Denials	0	0	0	0	0
Approval Decision Subtotal	**61**	**48**	**79**	**81**	**68**
Total PMA Actions	**280**	**266**	**320**	**282**	**236**
Average Review Time (Days) for Approvals[b]					
FDA	158	154	173	129	160
Non-FDA	41	26	41	43	53
Total	**199**	**180**	**214**	**172**	**213**
Average Elapsed Time (Days) for Approvals[c]					
FDA	291	316	254	257	259
Non-FDA	122	118	114	154	105
Total	**413**	**434**	**368**	**411**	**364**
Number under Review at End of Period[d]					
Active[e]	62	68	45	46	34
(Active and Overdue)	(35)	(27)	(10)	(6)	0
On Hold[f]	43	40	39	39	31
Total	**105**	**108**	**84**	**85**	**65**

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

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

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

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

e/ FDA responsible for processing application.

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

Table 5. Original PMA Receipt Cohort Performance*
FY 98– FY 02

	FY98	FY99	FY00	FY01	FY02
Original PMAs Filed					
PMAs	32	48	60	58	12
Expedited PMAs	6	7	8	9	4
Total	**38**	**55**	**68**	**67**	**16**
Filing Decisions[a]					
Filed	38	55	68	67	16
Not Filed	3	1	3	3	0
Number (%) of Filing/Not Filing Decisions within 45 Days	30(73)	44(79)	54(76)	47(66)	13(81)
Average Days/Cycle	44	42	41	44	43
Final Actions[b]					
Approvals	26	52	43	43	3
Denials	0	0	0	0	0
Other[c]	20	12	21	13	4
Total	**46**	**64**	**64**	**56**	**7**
Filing to First Action Excluding withdrawals, conversions, etc.[d]					
Number Received and Filed	38	55	68	67	16
Number of First Actions	37	55	63	67	16
Average FDA Days	134	145	132	132	126
Median FDA Days	145	147	143	133	126
Number (%) of First Actions with 180 Days	32(86)	43(78)	63(100)	65(97)	15(94)
Filing to First Action Including withdrawals, conversions, etc.[e]					
Number Received and Filed	38	55	68	67	16
Number of First Actions	38	55	68	67	16
Average FDA Days	134	145	133	132	126
Median FDA Days	141	147	136	133	126
Number (%) of First Actions with 180 Days	33(87)	43(78)	68(100)	65(97)	15(94)
Filing to Final Action Excluding withdrawals, conversions, etc.[f]					
Number Received and Filed	38	55	68	67	16
Number of Final Actions	28	49	46	43	3
Average FDA (Total) Elapsed Time	235(362)	277(394)	222(326)	218(265)	203(209)
Median FDA (Total) Elapsed Time	198(220)	251(354)	181(280)	182(234)	178(180)
Number (%) of Final Actions with 180 FDA Days	12(43)	8(16)	22(48)	19(44)	2(67)
Number (%) of Final Actions with 180 Total Days	10(36)	5(10)	7(15)	11(26)	2(67)
Filing to Final Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	38	55	68	67	16
Number of Final Actions	37	55	66	51	3
Average FDA (Total) Elapsed Time	247(448)	274(424)	205(356)	208(294)	203(209)
Median FDA (Total) Elapsed Time	181(289)	252(372)	179(284)	181(263)	178(180)
Number (%) of Final Actions with 180 FDA Days	19(51)	10(18)	40(61)	25(49)	2(67)
Number (%) of Final Actions with 180 Total Days	11(30)	5(9)	12(18)	11(22)	2(67)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[b]	1.7	2.1	1.6	1.5	1.3

(Continued on next page.)

Table 5. Original PMA Receipt Cohort Performance*
FY 98 – FY 02

(Continued from previous page.)

	FY98	FY99	FY00	FY01	FY02
Percentile FDA Days from Filing to First Action[d]					
25th	99	115	99	105	109
50th (Median)	145	147	143	133	126
75th	175	179	177	176	157
90th	192	227	180	179	178
Percentile FDA Days from Filing to First Action[c]					
25th	99	115	99	105	109
50th (Median)	141	147	136	133	126
75th	174	179	175	176	157
90th	181	227	179	179	178
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	154(158)	207(253)	175(205)	176(179)	162(178)
50th (Median)	198(220)	251(354)	181(280)	182(234)	178(180)
75th	328(476)	330(491)	278(424)	261(327)	270(270)
90th	392(915)	405(660)	341(498)	335(418)	270(270)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	141(178)	201(254)	162(204)	165(180)	162(178)
50th (Median)	181(289)	252(372)	179(284)	181(263)	178(180)
75th	289(684)	327(587)	272(460)	259(357)	270(270)
90th	392(940)	404(757)	319(721)	311(475)	270(270)
Active	0	0	1	6	8
(Active and Overdue)	0	0	0	0	0
On Hold[h]	2	0	2	9	5
Total	**2**	**0**	**3**	**15**	**13**
Summary of PMA Receipt Cohort					
Approved	26	52	43	43	3
Denied	0	0	0	0	0
Withdrawn	11	6	16	11	2
Other	9	6	5	2	2
Under Review	0	0	1	6	8
On Hold[h]	2	0	2	9	5
Total	**48**	**64**	**67**	**71**	**20**

*/ For each fiscal year, September 30, 2002 was used as the cutoff date. The FY02 cohort represents only receipts through March 31, 2002 (first 6 months of the fiscal year). The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus the average elapsed time is the average time taken to obtain approval of a PMA from its filing date until it receives final approval.

(Continued on next page.)

Table 5. Original PMA Receipt Cohort Performance FY 98 – FY 02

(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 98 - FY 02

	FY98	FY99	FY00	FY01	FY02
Number Received	517	557	546	641	644
PMA Supplement Actions					
Panel Track Filing Decisions[a]					
Filed	15	17	15	11	23
Not Filed	2	2	3	4	1
Other	0	0	0	0	0
Filing Decision Subtotal	**17**	**19**	**18**	**15**	**24**
Scientific Review Decisions					
Major Deficiencies	4	12	13	9	12
Minor Deficiencies	2	0	1	0	0
Other[b]	72	76	83	78	93
Scientific Review Decisions Subtotal	**78**	**88**	**97**	**87**	**105**
Approval Decisions					
Panel Track Approvals[c]	5	11	11	11	16
Nonpanel Track Approvals	416	429	463	431	516
Approvable	91	95	100	100	102
Not Approvable	63	62	59	52	51
Approval Decision Subtotal	**575**	**597**	**633**	**594**	**685**
Total PMA Supplement Actions	**670**	**704**	**748**	**696**	**814**
Average Review Time (Days) for Approvals[d]					
FDA	82	76	76	71	85
Non-FDA	25	18	18	26	20
Total	**107**	**94**	**94**	**97**	**105**
Average Elapsed Time (Days) for Approvals[e]					
FDA	109	92	95	78	96
Non-FDA	43	27	26	32	28
Total	**152**	**119**	**121**	**110**	**124**
Number Under Review at End of Period[f]					
Active[g]	143	156	99	154	126
(Active and Overdue)	(2)	(2)	(1)	(8)	0
On Hold[h]	56	65	82	95	98
Total	**199**	**221**	**181**	**249**	**224**

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 98 - FY 02

(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 98 - FY 02

	FY98	FY99	FY00	FY01	FY02
PMA Supplements Filed					
PMA Supplements	501	530	533	623	345
Expedited PMA Supplements	1	2	1	0	0
Total	**502**	**532**	**534**	**623**	**345**
PMA Supplement Final Actions[a]					
Approvals	421	442	420	465	263
Denials	0	0	0	0	0
Other[b]	81	92	101	138	50
Filing to First Action Excluding withdrawals, conversions, etc.[c,d]					
Number Received and Filed	502	532	534	623	345
Number of First Actions	482	513	517	602	329
Average FDA Days	81	72	63	71	72
Median FDA Days	57	36	37	36	36
Number (%) of First Actions within 180 Days	436(90)	464(90)	505(98)	569(95)	316(96)
Filing First Action Including withdrawals, conversions, etc.[e]					
Number Received and Filed	502	532	534	623	345
Number of First Actions	500	532	532	620	343
Average FDA Days	80	73	64	71	75
Median FDA Days	47	35	35	35	36
Number (%) of First Actions within 180 Days	453(91)	481(90)	520(98)	586(95)	326(95)
Filing to Final Action Excluding withdrawals, conversions, etc.[f]					
Number Received and Filed	502	532	534	623	345
Number of First Actions	455	488	493	574	294
Average FDA (Total) Review Days	91(115)	77(107)	68(90)	76(93)	70(78)
Median FDA (Total) Review Days	46(65)	34(47)	33(42)	33(42)	35(38)
Number (%) of Final Actions within 180 Days	376(83)	424(87)	464(94)	517(90)	276(94)
Number (%) of Final Actions within 180 Total Days	352(77)	402(82)	437(89)	490(85)	273(93)
Filing to Final Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	502	532	534	623	345
Number of First Actions	498	529	521	602	313
Average FDA (Total) Review Days	94(129)	85(129)	69(98)	77(96)	72(83)
Median FDA (Total) Review Days	49(68)	36(55)	35(43)	33(43)	35(41)
Number (%) of Final Actions within 180 Days	411(83)	455(86)	491(94)	542(90)	291(93)
Number (%) of Final Actions within 180 Total Days	371(74)	420(79)	454(87)	509(85)	284(91)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[a]	1.1	1.1	1.1	1.0	1.0

(Continued on next page.)

Table 7. PMA Supplement Receipt Cohort Performance*
FY 98 - FY 02

(Continued from previous page.)

	FY98	FY99	FY00	FY01	FY02
Percentile FDA Days from Filing to First Action[d]					
25th	22	19	21	25	22
50th (Median)	57	36	37	36	36
75th	169	147	113	127	140
90th	183	189	176	180	180
Percentile FDA Days from Filing to First Action[e]					
25th	22	19	20	24	22
50th (Median)	47	35	35	35	36
75th	155	135	109	120	135
90th	180	180	168	178	178
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	22(25)	18(24)	19(25)	24(27)	21(27)
50th (Median)	46(65)	34(47)	33(42)	33(42)	35(38)
75th	173(178)	138(154)	105(123)	123(145)	118(136)
90th	202(279)	190(236)	176(190)	180(204)	178(178)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	22(24)	19(25)	20(25)	23(27)	21(27)
50th (Median)	49(68)	36(55)	35(43)	33(43)	35(41)
75th	174(181)	146(168)	110(139)	123(151)	121(143)
90th	203(314)	196(280)	176(209)	180(209)	178(180)
Number Pending as of 9/30/01					
Active	0	0	0	2	8
(Active and Overdue)	0	0	0	0	0
On Hold[h]	4	3	13	19	24
Total	**4**	**3**	**13**	**21**	**32**
Summary of PMA Supplement Receipt Cohort					
Approved	421	442	420	465	263
Denied	0	0	0	0	0
Withdrawn	30	38	24	27	16
Other	51	54	77	111	34
Under Review	0	0	0	2	8
On Hold[h]	4	3	13	19	24
Total	**506**	**537**	**534**	**624**	**345**

*/ For each fiscal year, September 30, 2002 was used as the cutoff date. The FY02 cohort represents only receipts through March 31, 2002 (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 98 - FY 02

(Continued from previous page.)

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

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

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

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*
FY98 – FY02

	FY98	FY99	FY00	FY01	FY02
PMA Panel Track Supplements Filed					
Panel Track PMA Supplements	9	11	8	13	12
Expedited Panel Track PMA Supplements	0	4	3	1	3
Total	**9**	**15**	**11**	**14**	**15**
Filing Decisions[a]					
Filed	9	15	11	14	15
Not Filed	1	0	1	2	1
Number of Filing/Not Filing Decisions with 45 Days	9	10	10	14	11
Average Days/Cycle	42	45	39	38	50
PMA Panel Track Supplement Final Actions[b]					
Approvals	9	14	6	10	9
Denials	0	0	0	0	0
Other[c]	2	4	4	2	0
Filing to First Action Excluding withdrawals, conversions, etc.[d]					
Number Received and Filed	9	15	11	14	15
Number of First Actions	9	15	11	14	15
Average FDA Days	116	134	119	136	128
Median FDA Days	106	162	135	135	148
Number (%) of First Actions within 180 Days	7(78)	13(87)	10(91)	13(93)	14(93)
Filing First Action Including withdrawals, conversions, etc.[e]					
Number Received and Filed	9	15	11	14	15
Number of First Actions	9	15	11	14	15
Average FDA Days	116	134	119	136	128
Median FDA Days	106	162	135	135	148
Number (%) of First Actions within 180 Days	7(78)	13(87)	10(91)	13(93)	14(93)
Filing to Final Action Excluding withdrawals, conversions, etc.[f]					
Number Received and Filed	9	15	11	14	15
Number of First Actions	8	13	6	9	9
Average FDA (Total) Review Days	287(343)	274(327)	214(231)	214(255)	183(203)
Median FDA (Total) Review Days	237(269)	199(252)	214(248)	180(180)	187(216)
Number (%) of Final Actions within 180 Days	1(13)	5(38)	2(33)	5(56)	4(44)
Number (%) of Final Actions within 180 Total Days	0(0)	4(31)	2(33)	4(44)	3(33)
Filing to Final Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	9	15	11	14	15
Number of First Actions	9	14	10	10	9
Average FDA (Total) Review Days	275(374)	272(321)	255(363)	210(252)	183(203)
Median FDA (Total) Review Days	232(296)	217(244)	226(304)	180(203)	187(216)
Number (%) of Final Actions within 180 Days	2(22)	6(43)	3(30)	6(60)	4(44)
Number (%) of Final Actions within 180 Total Days	0(0)	4(29)	2(20)	4(40)	3(33)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[b]	1.8	2.0	1.8	1.5	1.3

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Table 8. PMA Panel Track Supplement Receipt Cohort Performance* FY98 – FY02

(Continued from previous page.)

	FY98	FY99	FY00	FY01	FY02
Percentile FDA Days from Filing to First Action[d]					
25th	87	84	88	81	67
50th (Median)	106	162	135	135	148
75th	175	179	157	174	175
90th	227	185	175	180	176
Percentile FDA Days from Filing to First Action[e]					
25th	87	84	88	81	67
50th (Median)	106	162	135	135	148
75th	175	179	157	174	175
90th	227	185	175	180	176
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	229(235)	179(179)	144(144)	174(174)	171(175)
50th (Median)	237(269)	199(252)	214(2480	180(180)	187(216)
75th	355(474)	385(385)	266(295)	248(283)	200(223)
90th	484(560)	450(494)	313(313)	313(539)	216(254)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	227(237)	179(179)	144(209)	174(174)	171(175)
50th (Median)	232(296)	217(244)	226(304)	180(203)	187(216)
75th	261(484)	385(385)	313(510)	248(283)	200(223)
90th	484(621)	450(494)	451(709)	301(440)	216(254)
Number Pending as of 9/30/02					
Active	0	0	1	2	5
(Active and Overdue)	0	0	0	0	0
On Hold[h]	0	2	1	3	0
Total	**0**	**2**	**2**	**5**	**5**
Summary of PMA Supplement Receipt Cohort					
Approved	9	14	6	10	9
Denied	0	0	0	0	0
Withdrawn	1	3	4	2	0
Other	1	1	0	0	0
Under Review	0	0	1	2	5
On Hold[h]	0	2	1	3	0
Total	**11**	**20**	**12**	**17**	**14**

*/ For each fiscal year, September 30, 2002 was used as the cutoff date. The FY02 cohort represents only receipts through March 31, 2002 (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* FY98 – FY02

(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 FY98 – FY02

TYPE OF SUBMISSION	NUMBER RECEIVED				
	FY98	FY99	FY00	FY01	FY02
Humanitarian Device Exemptions (HDEs)					
Original Applications	8	12	11	5	5
Amendments	32	55	56	62	54
Supplements	0	4	10	16	16
Amendments to Supplements	0	3	12	8	20
Reports for Original Applications	0	6	9	24	29
Reports for Supplements	0	0	0	0	0
Total	**40**	**80**	**98**	**115**	**124**

Table 10. Original HDE Decision Cohort Performance
FY98 – FY02

	FY 98	FY 99	FY 00	FY 01	FY 02
Number Received	8	12	11	5	5
HDE Action					
Filing Decisions					
Filed	9	10	8	6	6
Not Filed	1	1	4	1	1
Others[a]	1	1	0	0	0
Filing Decisions Subtotal	**11**	**12**	**12**	**7**	**7**
Scientific Review Decisions					
Major Deficiencies	0	6	7	7	6
Minor Deficiencies	1	0	3	6	2
Other[b]	0	4	6	2	0
Scientific Review Decisions Subtotals	**1**	**10**	**16**	**15**	**8**
Approval Decisions					
Approvals	4	6	6	4	6
Approvable	0	5	1	0	0
Not Approvable	0	0	0	0	0
Denials	0	0	0	0	0
Approved Decision Subtotal	**4**	**11**	**7**	**4**	**6**
Other Final Decisions[c]	2	4	1	4	2
Total HDE Actions	**18**	**37**	**36**	**30**	**23**
Filing to First Action[d]					
Number of First Actions	6	13	8	6	6
Average Number of FDA Days	139	87	61	42	53
Number of First Actions Within 75 Days	1	7	8	6	5
Average Elapsed Time (Days) for Approvals[e]					
FDA	152	113	112	143	175
Non-FDA	0	50	104	100	127
Total	**152**	**163**	**216**	**243**	**302**
Average Number of FDA Cycles from Receipt to Final Action[f]	1.2	1.2	1.3	1.9	2.1
Number under Review at End of Period[g]					
Active[h]	3	2	2	1	1
Active and Overdue	0	0	0	0	0
On Hold[i]	1	8	8	6	3
Total	**4**	**10**	**10**	**7**	**4**

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.

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Table 10. Original HDE Decision Cohort Performance
FY98 – FY02

(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 FY98 – FY02

	FY98	FY99	FY00	FY01	FY02
Number Received	0	4	10	16	16
HDE Supplement Actions					
Scientific Review Decisions					
Major Deficiencies	0	1	0	0	0
Minor Deficiencies	0	0	0	0	0
Other[a]	0	2	0	1	1
Scientific Review Decisions Subtotal	**0**	**3**	**0**	**1**	**1**
Approval Decisions					
Approvals	0	3	10	11	13
Approvable	0	1	0	0	6
Not Approvable	0	0	1	1	6
Denials	0	0	0	0	0
Approval Decision Subtotal	**0**	**4**	**11**	**12**	**25**
Other Final Decisions[b]	0	0	0	1	1
Total HDE Actions	**0**	**7**	**11**	**13**	**27**
Filing to First Action[c]					
Number of First Actions	0	4	10	12	17
Average Number of FDA Days	0	57	44	52	53
Number of First Actions within 75 Days	0	4	10	8	16
Average Elapsed Time (Days) for Approvals[d]					
FDA	0	70	43	46	60
Non-FDA	0	24	33	0	14
Total	**0**	**94**	**76**	**46**	**74**
Average Number of FDA Cycles from Receipt to Final Action[e]	0.0	1.3	1.0	1.0	1.3
Number Under Review at End of Period[f]					
Active[g]	0	0	0	4	4
(Active and Overdue)	0	0	0	0	0
On Hold[h]	0	1	1	1	4
Total	**0**	**1**	**1**	**5**	**8**

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.

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Table 11. HDE Supplement Decision Cohort Performance FY98 – FY02

(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 98 - FY 02

	FY98	FY99	FY00	FY01	FY02
Number Received	322	304	311	284	312
Number of Decisions Approved	201	176	213	208	209
Not Approved	82	82	66	53	75
Other[a]	42	47	41	23	23
Total	**325**	**305**	**320**	**284**	**307**
Percent (%) of Approvals Made during First Review Cycle[b]	71	68	76	80	74
Average FDA Review Time (days)	27	27	28	28	28
Percent (%) of Decisions Made within 30 Days	100	99	99	100	99
Number under Review at End of Period[c]	29	28	19	18	22
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 98 - FY 02

	FY98	FY99	FY00	FY01	FY02
Amendments Received[a]	226	275	240	206	252
Decisions on Amendments					
Approved	94	97	107	73	86
Not Approved	36	42	34	39	55
Other[b]	95	129	110	95	110
Total	**225**	**268**	**251**	**207**	**251**
Average FDA Review Time (days)	19	18	19	18	18
Percent (%) of Decisions Made within 30 Days	100	100	100	99	100
Average Approval Time (days) For IDEs with Amendments					
FDA Time	55	57	70	59	68
Non-FDA Time	35	88	66	82	67
Total Time[c]	**90**	**145**	**136**	**141**	**135**
Number of Amendments per Approved IDE	1.4	1.6	2.3	1.7	2.2
Amendments under Review at End of Period[d]	13	19	9	8	7
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 98 - FY 02

	FY98	FY99	FY00	FY01	FY02
Number Received	4,277	4,127	4,388	4,811	4,724
Number of Decisions	4,209	4,224	4,335	4,803	4,711
Average FDA Review Time (days)	21	20	20	21	20
Percent (%) OF Decisions Made within 30 Days	100	100	100	100	100
Number under Review at End of Period[a]	284	187	239	247	260
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 98 - FY 02

	FY98	FY99	FY00	FY01	FY02
Number Originals Received	4,623	4,458	4,202	4,248	4,320
Number of Decisions					
Substantially Equivalent	3,824	3,652	3,567	3,428	3,667
Not Substantially Equivalent	65	66	52	46	69
Other[a]	1,340	875	778	676	640
Total	**5,229**	**4,593**	**4,397**	**4,150**	**4,376**
Percent (%) Not Substantially Equivalent[b]	1.7	1.8	1.4	1.3	1.8
Average Review Time (Days)					
FDA Time[c]	89	80	77	75	79
Total Time[d]	114	102	102	96	100
Median Review Time (Days)					
FDA Time[c]	81	71	68	68	70
Total Time[d]	83	76	72	72	74
Percent (%) of Decisions made within 90 Days, based on					
FDA Time[e]	97	99	100	100	100
Total Time[d]	59	66	66	69	69
Number under Review at End of Period[f]					
Active[g]	1,057	943	850	934	935
(Active and Overdue)	0	0	0	0	0
On Hold[h]	487	461	370	382	337
Total	**1,544**	**1,404**	**1,220**	**1,316**	**1,272**

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 98 - FY 02

	FY98	FY99	FY00	FY01	FY02
Number of 510(k)s Received[a]					
Traditional	4,528	3,985	3,471	3,370	2,467
Special	80	396	584	710	562
Abbreviated	21	85	149	174	136
Total Receipts	**4,629**	**4,466**	**4,204**	**4,254**	**3,165**
Actions on 510(k)s					
Substantially Equivalent	3,573	3,605	3,423	3,545	2,336
Not Substantially Equivalent (%)[b]	70(1.9)	63(1.7)	44(1.3)	58(1.6)	35(1.5)
Other[c]	986	798	737	602	354
Total Actions	**4,629**	**4,466**	**4,204**	**4,205**	**2,725**
Average Cumulative Days for 510(k) Decisions					
Excludes Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	82	81	75	78	65
Total Time from Receipt to Final Decision[e]	104	104	95	96	73
All Decisions Including Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	81	79	74	76	64
Total Time from Receipt to Final Decision[e]	118	114	104	102	76
Number of Decisions (%) with 90 Days, Based on:					
FDA Days from Receipt to First Action	4,612(100)	4,453(100)	4,198(100)	4,245(100)	3,158(100)
FDA Cumulative Days from Receipt to Final Decisions	3,529(76)	3,372(76)	3,370(80)	3,258(77)	2,375(75)
Total Cumulative Days from Receipt to Final Decisions[e]	3,025(65)	2,938(66)	2,916(69)	2,889(68)	2,206(70)
Average Number of FDA Cycles from Receipt to Final Action	1.4	1.4	1.4	1.4	1.2
Percentile FDA (Total) Days from Receipt to Final Action					
25th	47(51)	41(45)	35(41)	31(35)	32(35)
50th (Median)	75(83)	71(78)	65(73)	70(77)	71(77)
75th	90(149)	90(147)	89(126)	90(145)	90(138)
90th	160(256)	160(263)	153(238)	164(237)	N/A(N/A)
Number under Review as of 9/30/01					
Active	0	0	0	22	199
Active and Overdue	0	0	0	0	0
On Hold	0	0	0	27	241
Total	**0**	**0**	**0**	**49**	**440**
Summary of 510(k) Receipt Cohort					
Substantially Equivalent	3,573	3,605	3,423	3,545	2,336
Not Substantially Equivalent	70	63	44	58	35
Other	986	798	737	602	354
Under Review	0	0	0	22	199
On Hold	0	0	0	27	241
Total	**4,629**	**4,466**	**4,204**	**4,254**	**3,165**

(Continued on next page.)

Table 16. 510(k) Receipt Cohort Performance*
FY 98 – FY 02

(Continued from previous page.)

*/ For each fiscal year, September 30, 2002 was used as the cutoff date. The FY02 cohort represents only receipts through June 30, 2002 (first nine months of the fiscal year).

a/ Includes Third Party 510(k)s: FY98 =18; FY99 = 32; FY00 = 47; FY01 =70; FY02 = 95

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

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

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

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

Appendix A – Summary of Major ODE Programs

ODE is responsible for the program areas through which medical devices are evaluated 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 2002.

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Ho, C. Challenges in Designing a Multi-Function Patient Monitor. *Biomedical Sciences Instrumentation* 38:71-76, 2002.

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Staff College Presenters and Faculty

Abel, Dorothy
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Lacy, Frank
Less, Joanne
McCool, Barbara
Melkerson, Mark
Mitchell, Diane
Morris, Janine
Moynahan, Megan
Nell, Diane
Nutter, Cathy
Nguyen, Thinh
Phillips, Robert
Provost, Miriam
Rosecrans, Heather
Sacks, William
Stewart, Sandy
Swain, Julie
Tillman, Donna-Bea
Virmani, Mridulika
Warburton, Karen
Whang, Joyce
Witten, Celia
Yustein, Ron

Appendix C – Selected FDA Websites

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

Appendix D – ODE Organization Chart

as of 11/08/02

OFFICE OF THE DIRECTOR

Director: Daniel G. Schultz, M.D.
Deputy Director, Science & Regulatory Policy: Philip Phillips
Integrity Officer: Carl DeMarco, J.D.
Panel Coordinator: Nancy Pluhowski

PROGRAM OPERATIONS STAFF (POS)

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

PROGRAM MANAGEMENT OFFICE (PMO)

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

DIVISION OF CARDIOVASCULAR DEVICES (DCD)

Director: Bram Zuckerman, M.D.
Deputy Director I: Donna-Bea Tillman, Ph.D.
Deputy Director II: Vacant
Associate Director, Guidance & Policy: Arthur Ciarkowski
Clinical Trials Coordinator: Wolf Sapirstein, M.D.
Pacing, Defibrillator, And Leads Branch: Megan Moynahan
Cardiac Electrophysiology And Monitoring Devices Branch: Elias Mallis
Interventional Cardiology Devices Branch: Ashley Boam
Circulatory Support & Prosthetic Devices Branch: Dina Fleischer*
Peripheral Vascular Devices Branch: Elisa Harvey, D.V.M., Ph.D.

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

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

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

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

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

Director: Celia Witten, M.D.
Deputy Director I: Mark Melkerson
Deputy Director II: Miriam C. Provost, Ph.D.
Plastic & Reconstructive Surgery Devices Branch: Stephen Rhodes
General Surgery Devices Branch: Neil Ogden
Orthopedic Devices Branch: Barbara Zimmerman
Restorative Devices Branch: Theodore Stevens

DIVISION OF CLINICAL LABORATORY DEVICES (DCLD)

Director: Steven Gutman, M.D.
Deputy Director : Donald St. Pierre
Associate Director, Special Programs: Joseph Hackett, Ph.D.
Associate Director, 510(K) & Outreach Program: Kaiser Aziz, Ph.D.
Chemistry And Toxicology Devices Branch I: Jean Cooper, D.V.M.
Chemistry And Toxicology Devices Branch II: Jean Cooper, D.V.M.*
Immunology And Molecular Diagnostics Devices Branch: James Reeves
Hematology And Cytology Devices Branch: Josephine Bautista
Virology Devices Branch: Freddie Poole*
Bacteriology Devices Branch: Freddie Poole

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

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

*Acting

Appendix E - ODE Staff Roster

Office of the Director

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

Program Management Office

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

Program Operations Staff

Berk, Gene
Fisher, Lisa
Garcia, Diane
Gatling, Robert
Hawthorne, C. Ann
Less, Joanne
Lyons-Drager, Linda
Melvin, Marsha
Nguyen, Thinh
Parker, Mervin
Rechen, Eric
Romanell, Lawrence
Rosecrans, Heather
Sawyer-Major, Wanda
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
Callaghan, Jim
Calvin, Veronica
Carlos, Rufina
Chace, Nina
Chan, Maria
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
Hausman, Ethan
Heyliger, Marian
Hoard, Renita
Hyde, John
Ingram, Jr., Kenneth
Jones, Doris
Kellerman, Christine
King, Lisa

Lyle, Dave
MacArthy, Philip
Magruder, Louise
Mansfield, Elizabeth
McClain-Bennett, Joan
Michaud, Ginette
Moore, Deborah
Moxey-Mims, Marva
Pinkos, Arleen
Poneleit, Kathy
Poole, Freddie
Radha, Edappallath
Rao, Prasad
Reeves, Pat
Robinowitz, Max
Rogers, Liz
Schoonmaker, Michelle
Selepak, Sally
Shaikh, Farzana
Shively, Roxanne
Simms, Tom
Sliva, Clara
St. Pierre, Don
Summers, Peter
Torres Cabassa, Angel
Tsai, Miin-Rong
Weeks, Susan
Wei, Tena
Whitaker, Kathleen
Wilbon, Tonya
Wright, Kathy

Division of Cardiovascular Devices

Abel, Dorothy
Barold, Helen
Berman, Michael
Boam, Ashley
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
Foreman, Christy
Foy, Joni
Foy, Keith
Gantt, Doyle
Goode, Jennifer
Harvey, Elisa
Hayden, Brenda
Heaton, Tom
Ho, Charles
Hoang, Quyun
Holden, John
Holt, Vivianne
Hottenstein, Omar
Huynh, Ann
Hwang, Shang
Hyde, John
Jensen, Nick
Jones, Edwena
Kaiser, Suzanne
Kennell, Lisa
Kurtzman, Steve
Lacy, Frank
Lee, James
Lemperle, Bette
Letzing, Bill
Lyle, Judy
Mallis, Elias
Moynahan, Megan
Muni, Neal
Nell, Diane
Peters, Kimberly
Portnoy, Stuart
Ramdat, Deb
Roy, Joydeb
Ryan, Tara
Samadnejad, Sami
Sapirstein, Wolf
Shein, Mitchell
Smallwood, Senora

Smith, Angela
Staschen, Carl-Michael
Stuhlmuller, John
Swain, Julie
Terry, Doris
Tillman, Donna-Bea
Ulmer, Kwame
Usher, Wil
Vaughan, Carolyn
Wentz, Catherine
Wood, Geretta
Zuckerman, Bram

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

Adjodha, Michael
Barrett, Sue
Bazaral, Mike
Betz, Robert
Bezabeh, Shewit
Blackwell, Angela
Blount, Sharon
Bolden, Brenda
Browne, Myra
Burdick, William
Cricenti, Pat
Cunningham, Terrell
Dorsey, Regina
Floyd, Chirelle
Fox, Pat
Gantt, Gail
Harris, Lisa
Hibbard, Viola
Lin, Chiu
Marshall, Felicidad
Mayhall, Elaine
Mulry, Kevin
Nakayama, Von
Naveau, Irene
Noe, Bill
O'Connell, Linh
O'Lone, Martha
Patel, Hina
Reid, Joy
Robinson, Mary Jo
Roy, Joydeb
Runner, Susan
Sauberman, Harry
Scott, Pam
Smith, Gwendolyn
Soprey, Pandu
Teresinski, Doris
Turtil, Steve
Ulatowski, Tim
Weitershausen, Joanna

Division of General, Restorative, and Neurological Devices

Adjodha, Michael
Allen, Peter
Allen, Samie
Anderson, Jodi
Arepalli, Sam
Ashar, Binita
Basu, Sankar
Berkowitz, David
Bernato, Dolores
Berne, Bernard
Bourke, Tracey
Bowsher, Kristen
Buch, Barbara
Corn, David
Costello, Ann
Courtney, Mike
Dawisha, Sahar
De Del Castillo, Sergio
DeLuca, Bob
Demian, Hany
Durfor, Charles
Einberg, Elmar
Eudy, Mike
Felten, Richard
Fogarty, Pauline
Foy, Keith
Gantenberg, Julie
Goode, John
Hackey, Elise

Hammond, Della
Hinckley, Steve
Horbowyj, Roxi
Hudson, Peter
Kaiser, Aric
Krause, David
Lee, Kevin
Linde-Feucht, Sarah
Mattamal, George
Mattera, Michelle
Melkerson, Mark
Mishra, Nirmal
Ogden, Neil
Pak, Yung
Phillips, Mary Ellen
Prasad, Srinivas
Provost, Miriam
Rhodes, Holly
Rhodes, Stephen
Rossi, Jeff
Schroeder, Marie
Scudiero, Jan
Segarra-Crowe, Livia
Sloan, Nadine
Stevens, Ted
Stiegman, Glenn
Sturniolo, Mike
Sung, Pei
Tudor, Natalie
Walker, Jeff
Warfield, Diane
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
Brown, Daniel
Burke-Nicholas, Marsha
Callaway, Jan
Calogero, Don
Chen, Tzeng
Cohen, Linda
Cygnarowicz, Teresa
Drum, Bruce
Eydelman, Malvina
Falls, Deborah
Glover, Joel
Gouge, Susan
Hilmantel, Gene
Hoang, Quynh
Jaffe, Sidney
Jones, Susanna
Kane, James
Kaufman, Daryl
Lepri, Bernard
Leslie, Sharmeka
Lochner, Donna
Malshet, Vasant
Mann, Eric
McCarthy, Denis
McGhee, Eleanor
Moore, Shirley
Nandkumar, Srinivas
Ortega, Maritze
Rorer, Eva
Rosenthal, Ralph
Saviola, James
Selfon, Eric
Shi, Dexiu
Shih, Ming-Chuen
Smith, Myra
Storer, Patricia
Thornton, Sara
Toy, Jeffrey
Warburton, Karen
Whipple, David

Division of Reproductive, Abdominal, and Radiological Devices

Arnaudo, Joe
Baxley, John
Bradley Allen, Cheryl
Brogdon, Nancy
Byrd, Laura
Carr, Linda
Chen, John
Cooper, Jeff
Cornelius, Mary Jo
Corrado, Julia
Czerska, Ewa
Dart, Linda
Daws-Kopp, Kathryn
Doyle, Bob
Eba, Felisa
Gonzalez, Gema
Harvey, Brian
Herrera, Hector
Howell, Kimberly
Jevtich, Milorad
Kammula, Raju
Kang, Simkeon
Kuchinski, Mike
Lappalainen, Sharon
Lawrence, Lisa
Lutwak, Leo
Mackey, Cheryl
McCool, Barbara
Meyers, Catherine
Miller, Pat
Mitchell, Diane
Monahan, Jack
Morris, Janine
Neuland, Carolyn
Nipper, Joshua
Nimmagadda, Rao
Nutter, Cathy
O'Brien, Mary Beth
Olvey, Kathleen
Perez, Rod
Phillips, Bob
Pollard, Colin
Price, Veronica
Rubendall, Rita
Sacks, William
Sauls, Mattie
Segerson, Dave
Seiler, Jim
Shuping, Ralph
Straughn, Kellie
Virmani, Mridulika
Whang, Joyce
Williams, Dick
Zaremba, Loren
Zaudtke, Peter
Yustein, Ron