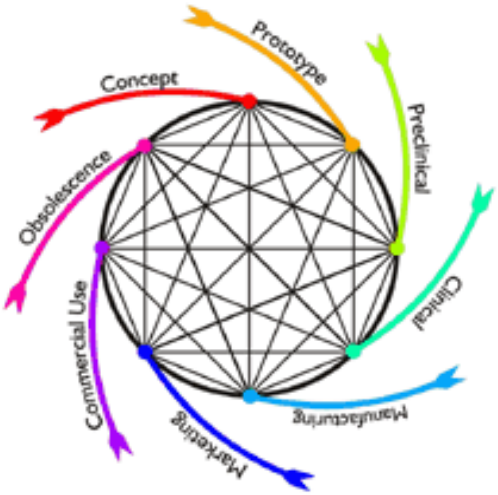
OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 2004



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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PREFACE

Dear Reader:

When we look back on our accompiishments for 2004, chief among them will be implementation of new processes to enable us to meet our MDUFMA goals. In keeping with the CDRH vision of Total Product Lifecycle, this involved a Center-wide effort to develop milestones for the pre-market review process. By creating a culture of shared commitment to these milestones, we will improve the timeliness of the premarket review process, and bring safe and effective products to market more quickly than ever. We have also used our MDUFMA resources to make much-needed improvements to several of our key IT systems, which has also improved our ability to manage our workload.

This year we have also strengthened our commitment to improving the quality of the science that underlies the premarket review program. The resources that MDUFMA provides have enabled us to continue to bring in many talented professionals, both as new hires and through the ever-expanding Medical Device Fellowship Program. MDUFMA has also allowed us to provide our staff with opportunities to refine their technical skills through attendance at training and scientific meetings. Through collaborations with other parts of CDRH, we have brought a new emphasis to guidance development and the use of voluntary standards.

This past year has seen much change for ODE. However, one thing has not changed, and that is the commitment that each and every one of us brings to our mission of promoting and protecting the public health. We look forward to working with all of our stakeholders in the coming years to ensure that we continue to be prepared to take on this important challenge.

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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 2004." 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.

Expandable Prosthetic Rib – The Vertical Expandable Prosthetic Titanium Rib (VEPTR) by Synthes (USA) was approved as a Humanitarian Use Device for conditions afflicting less than 4000 patients a year. VEPTR device is the first implant intended to treat Thoracic Insufficiency Syndrome (TIS) in skeletally immature pediatric patients. TIS is a congenital condition where severe deformities of the chest, spine, and ribs prevent normal breathing and lung growth and development. The VEPTR device is a curved metal rod that is attached to ribs near the spine using hooks located at both ends of the device.

The VEPTR device helps straighten the spine and separate ribs so that the lungs can grow and fill with enough air to breathe. During surgery, the VEPTR device is adjusted to fit the patient and attached vertically on the patient's ribs near the spine. Lengthening the device enlarges the rib cage and increases the amount of lung space in the patient's chest. The VEPTR device will be lengthened or replaced at specific times to allow for the patient's growth and to further correct spinal or chest wall deformity. Adjustments to the length of the VEPTR device are made during surgery through a small cut (incision) in the patient's back. Use of the VEPTR device in skeletally immature pediatric patients may result in:

- a more normal growth pattern without spinal growth limitations,
- decreased chest, spine and rib deformity,
- expanded lung volume, and
- decreased dependence on a supplemental air supply.

Rechargeable Spinal Cord Stimulator – Precision Spinal Cord Stimulator by Advanced Bionics is the first rechargeable implanted spinal cord stimulator which should require fewer replacement surgeries due to limited battery life. The PRECISION™ Spinal Cord Stimulator (SCS) System is a neurostimulation device that

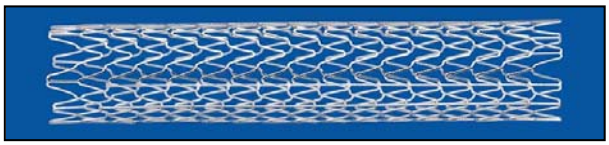
transmits electrical signals to the spinal cord to decrease chronic pain in the body, arms and legs.

The device consists of two parts: a stimulator device (signal generator) implanted under the skin that transmits electrical signals to the spinal cord through an insulated lead wire, and an external remote control that programs the treatment delivered by the signal generator. The implanted signal generator receives radio signals from the remote control.

The radio signals tell the signal generator when and what kind of stimulation to deliver to the spinal cord. The external remote control is battery operated and can be controlled by the patient or a health care provider. The Precision™ SCS System is used as an aid in the management of: difficult to treat chronic pain of the body and limbs, pain associated with failed back surgery syndrome, low back pain, and leg pain.

Dermal Filler – Sculptra Injectable filler by Dermik Laboratories is the first approved treatment for the effects of lipoatrophy (facial fat loss) in persons with HIV. The changes in facial appearance as a result of lipoatrophy are one of the stigmatizing side effects of the drugs used to treat HIV. Sculptra is a dermal filler made from absorbable poly-L-lactic acid (PLA). Sculptra was shown to produce significant increases in skin thickness, adding volume to facial tissue and restoring shape in areas of the face with fat loss. Studies reported an improvement in the quality of life among those treated and less of the anxiety and depression often associated with lipoatrophy.

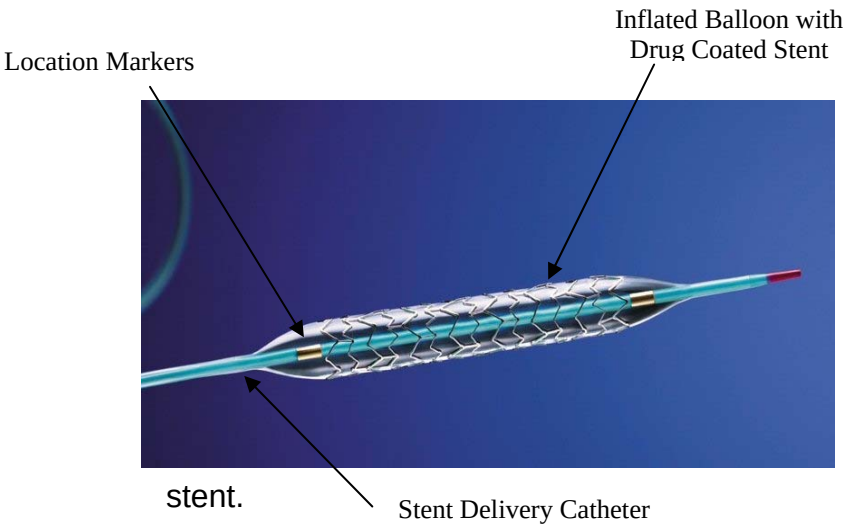
Carotid Stent System – The Acculink™ Carotid Stent System from Guidant was approved for use in opening blocked arteries in the neck. The new stent is intended to prevent stroke by treating blockages in the carotid artery, the main blood vessel leading to the brain. The device was approved for use in patients who have had symptoms of a stroke, or whose neck blood vessels are at least 80 percent blocked, and who are not good candidates for the surgical alternative.



The Acculink™ Carotid Stent System was approved with the Accunet™ Embolic Protection Device (K042218) also from Guidant Corporation. The

Accunet device is a filter device that opens up like an umbrella. It has small holes to allow blood to flow through, but small enough to catch any particles that may break off from the blockage during the stenting procedure.

Drug Coated Stent – The TAXUS™ Express^2™ Paclitaxel-Eluting Coronary Stent by Boston Scientific Corporation, is an expandable, slotted, stainless steel tube, with a drug (paclitaxel) contained within a thin polymer coating on its surfaces. The Stent is mounted over a deflated balloon attached to the end of a long thin flexible tube (*stent delivery catheter*). The Stent is used in patients who have a narrowing in their coronary arteries (blood vessels supplying blood to the heart) caused by atherosclerosis -- the collection of fatty substances such as cholesterol that forms "plaque" along the lining of the arteries. The TAXUS Express Stent should not be used in patients:



- who cannot take aspirin or blood-thinning medicine,
- who have an allergy to the drug paclitaxel, related drugs, or the polymers used to coat the stent, or
- who have a blockage in the coronary artery that will not allow complete inflation of the balloon or proper placement of the stent.

Implantable Therapy Defibrillators – The Guidant CONTAK CD, CONTAK CD2, RENEWAL, and RENEWAL 3 are implantable cardioverter defibrillators (ICDs) that also deliver cardiac resynchronization therapy (CRT). These ICDs use small electrical impulses to coordinate heart rhythm and improve blood pumping ability in certain patients with moderate to severe heart failure. A Guidant Cardiac Resynchronization Therapy Defibrillator (CRT-D) consists of an implantable pulse generator (IPG), made up of a battery and electronic circuitry, connected to three leads (insulated wires). The IPG is usually implanted below the collarbone, just beneath the skin. When the device is functioning as an ICD, it senses dangerous abnormal heart rhythms and attempts to shock the heart back into a normal rhythm. The CRT portion of the device coordinates the beating of the left and right ventricles so that

they work together more effectively to pump blood throughout the body. A Guidant CRT-D is used in certain patients who have:

- symptoms of advanced heart failure despite taking heart failure medication, and
- a heart rhythm problem (arrhythmia) that may cause the lower chambers of the heart to beat in an uncoordinated manner.

A Guidant CRT-D is indicated for patients with moderate to severe heart failure (NYHA III/IV) who remain symptomatic despite stable, optimal heart failure drug therapy, and have left ventricular dysfunction (EF </= 35%) and QRS duration >/= 120 ms.
A Guidant CRT-D will deliver:

- CRT to help coordinate the beating of the heart, and
- a life-saving shock to attempt to return the heart to normal heart rhythm.

Together, these two therapies may reduce the combined risk of death or first hospitalization as well as the risk of death alone. It may also relieve some of the symptoms associated with heart failure, including shortness of breath and fatigue during exercise, which may result in a better quality of life.

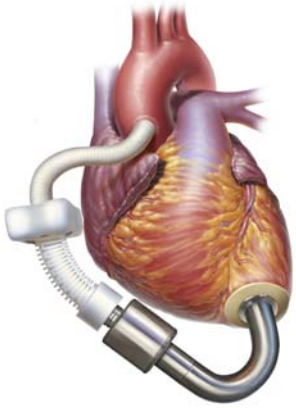
Home Defibrillator – The HeartStart Home Defibrillator by Philips Medical Systems is a small, lightweight automatic external defibrillator (AED) specifically designed for home use without a prescription. HeartStart is a battery-powered device that delivers an external electric shock through the patient's chest to help restore a normal heart rhythm. It is intended to treat a person who experiences sudden cardiac arrest caused more frequently by ventricular fibrillation. During ventricular fibrillation, the electrical signals in the lower part of the heart are uncoordinated and ineffective. Very little blood is pumped from the heart to the body or the lungs. If ventricular fibrillation is not treated it will result in death. The HeartStart Home Defibrillator can be used on an adult or child who:

- is 8 years of age or older,
- weighs at least 55 pounds,
- is in sudden cardiac arrest,
- does not respond when shaken, and
- is not breathing normally.

Special adhesive pads for use on infants and young children are available by prescription.

HeartStart is designed for consumer use in the home. CPR training is recommended for anyone who may use the HeartStart.

ADVANCES IN PATIENT CARE



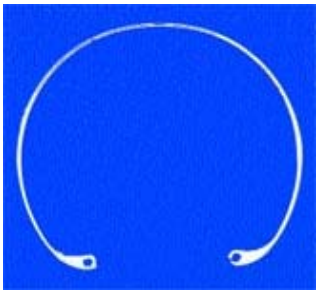
Heart Assist Device for Children - The DeBakey VAD *Child* Left Ventricular Assist System by MicroMed Technology, Inc. was approved as a Humanitarian Use Device for pediatric patients with end-stage left ventricular failure requiring temporary mechanical circulatory support as a bridge to cardiac transplantation. It is estimated that fewer than 100 children a year will be candidates for this new device. The Debakey VAD *Child* is the first device approved for children with severe left ventricle failure. The device is a miniaturized, implantable, titanium, axial flow pump for children aged 5 to 16 with a body surface area between $0.7m^2$ and $1.5m^2$.

A titanium inflow cannula connects the pump to the ventricular apex and a Vascutek Gelweave vascular graft (outflow conduit) connects the pump to the aorta. A cable assembly attached to the pump exits the right frontal portion of the body and attaches to an external controller system. This controller provides energy to the device causing it to pump blood. The controller is always connected to the batteries and may be connected to an external power supply.

The DeBakey VAD *Child* should not be used in pediatric patients:

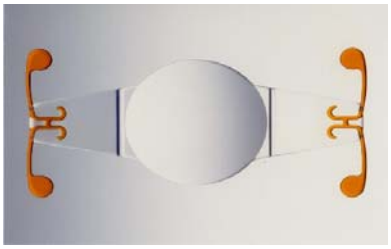
- who are under 5 years of age,
- who have a body surface area less than $0.7m^2$,
- who suffer from right ventricular failure unresolved by medical therapy,
- who have primary coagulopathy or platelet disorders, or
- who have an allergy or sensitivity to Heparin.

Capsular Tension Ring (CTR) - Morcher Capsular Tension Ring (CTR) manufactured by Morcher GmbH is the first CTR approved to help cataract surgeons place and center an intraocular lens (an artificial lens) in adult patients undergoing cataract surgery (a procedure to remove the clouded natural lens) and who have weakened or missing zonules (thin tissue fibers that hold the lens in place). Conditions associated with weak or missing zonules may include Marfan's Syndrome, Marchesani's Syndrome, trauma, etc.



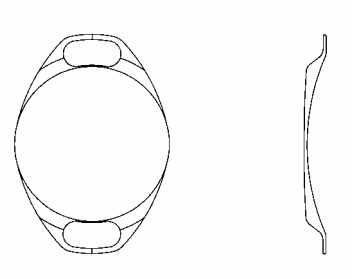
The CTR is a plastic ring circular in design; however, the circle is not complete due to positioning holes placed at the ends to help the surgeon position the device correctly in the capsule bag of the eye. The device is available in three sizes 14, 14A and 14C.

Accommodating Posterior Chamber IOL – Crystalens (Model AT-45) manufactured by Eyeonics is the first accommodative intraocular lens (IOL). The Crystalens is a modified plate haptic lens with polyimide loops and hinges across the plates next to the optic. The IOL is intended to be implanted in adults for the visual correction of aphakia



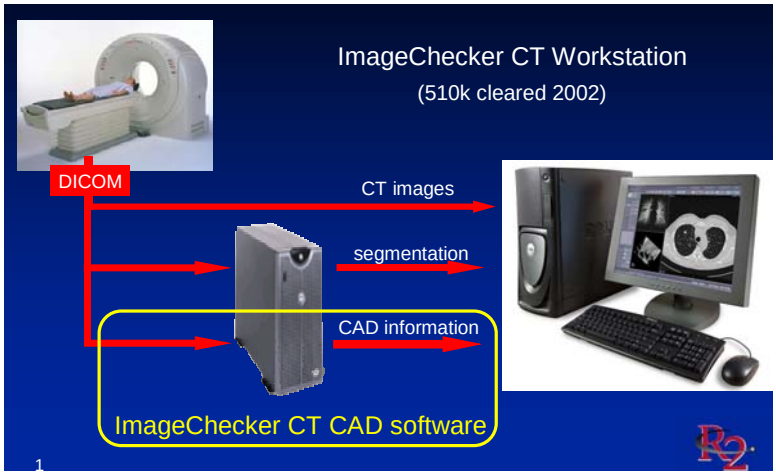
(absence of the natural crystalline lens) and to provide near, intermediate, and distance vision without spectacles and approximately one diopter of monocular accommodation. The exact mechanism of action is unknown; however, the lens design is to move back and forth along the axis of the eye in response to the movement of eye muscles thereby helping patients focus on objects.

Phakic Intraocular Lens (PIOL) - The ARTISAN® (Model 206 and 204) phakic intraocular lens (PIOL) manufactured by Ophtec is the first PIOL. This type of lens is called a PIOL because the eye still has its natural lens. The ARTISAN® PIOL is a permanently implanted plastic lens with haptics designed to attach to the iris. The ARTISAN® PIOL is intended to reduce or eliminate moderate to severe nearsightedness (myopia) ranging from -5.0 to -20.0 diopters (D) in patients aged 21 and over with less than or equal to 2.5 D of astigmatism, an anterior chamber depth greater than or equal to 3.2 millimeters, and a stable refraction (determined by an ophthalmologist). The ARTISAN® PIOL works by bending (refracting) light rays to allow them to focus on the retina.



Ophtec manufactures and distributes the lens under the trade name ARTISAN™ in all markets except North American and Japan. Advance Medical Optics (AMO) will distribute the device in North America and Japan under the name of Verisyse (Model VRSM5US and VRSM6US).

Image Analysis System – The ImageChecker® CT System by R2 Technology, Inc. is an image analysis system used by a radiologist to review Computed Tomography (CT) images of the chest. The system can help identify pulmonary nodules that a radiologist may have missed. The ImageChecker® CT System uses Computer Aided Detection (CAD) software to analyze CT images that a radiologist has reviewed. Following the radiologist's review of the case the software reviews the CT images to highlight suspect nodules (areas of interest) that he or she may have missed.



FDA Consumer Websites

Publicly Available Device Databases

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

Consumer Information

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

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

Part 2 – Industry Information

ODE 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 2004, 1 PDP was completed, and ODE approved 30 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 2004

		COMPANY	DEVICE
01-Oct-03	P030009	Medtronic Vascular	Driver™ Over the Wire Rapid Exchange and Multi-Exchange Coronary Stent System
07-Oct-03	P020050	SurgiVision® Refractive Consultants, LL	WaveLight ALLEGRETTO WAVE
10-Oct-03	P030008	WaveLight Laser Technologies	WaveLight Allegretto Laser for LASIK
23-Oct-03	P010059	Morcher GmbH	Morcher Capsular Tension Ring (CTR) Type: 14, 14A, 14C
24-Oct-03	P020040	Medinol Ltd.	NIRflex™ Pre-mounted Coronary Stent
14-Nov-03	P030002	Eyeonics, Inc.	Crystalens™ (Model AT-45) Accommodating Posterior chamber (PC) Intraocular lens (IOL)
21-Nov-03	H020003	Medtronic, Inc.	Contegra® Pulmonary Valved Conduit
12-Dec-03	P020023	Q-Med Scandinavia, Inc.	Restylane® Injectable Gel
12-Dec-03	P030039	Baxter Healthcare Corp.	CoSeal™ Surgical Sealant
26-Jan-04	P030005	Guidant Corp.	CONTAK® RENEWAL™
04-Feb-04	P030019	Anika Therapeutics, Inc.	Orthovisc® High Molecular Weight Hyaluronan
19-Feb-04	P030006	Celsion Corporation	Prolieve™ Thermodilation System, Transurethral Microwave Thermotherapy Device
24-Feb-04	H030004	Menssana Research, Inc.	Heartsbreath
25-Feb-04	H030003	MicroMed Technologies, Inc.	DeBakey VAD Child Ventricular Assist Device System

INDUSTRY INFORMATION

04-Mar-04	P030025	Boston Scientific Corp.	TAXUS™ Express^2 ™ Paclitaxel
15-Mar-04	P010058	Medilink	OSTEOSPACE™ Quantitative Ultrasound Bone Sonometer Device
07-Apr-04	H020008	Stryker Biotech	OP-1 Putty for Posterolateral Spinal Fusions
21-Apr-04	P010014	Biomet, Inc.	Oxford™ Meniscal Unicompartmental Knee System
22-Apr-04	P030032	Genzyme Corp.	Hylaform™ (Hylan B Gel)
27-Apr-04	P030017	Advanced Bionics Corp.	PRECISION™ Spinal Cord Stimulation(SCS) System
27-Apr-04	P030023	Ophtec USA, Inc.	Oculaid™ and Stableyes™ Capsular Tension Rings
30-Apr-04	P000054	Wyeth Pharmaceuiticals, Inc.	INFUSE® Bone Graft
13-May-04	P030035	St. Jude Medical	St. Jude Medical Frontier™ Biventricular Cardiac Pacing System
07-Jun-04	P010062	Euclid Systems Corp.	Euclid Systems Orthokeratology (Oprifocon A) Contact Lens
08-June-04	P030045	Ev3, Inc.	IntraStent® DoubleStrut™ Stent
17-Jun-04	P020030	ELA Medical, Inc.	Stelid II Steroid Eluting Pacing Lead
30-Jun-04	P030054	St. Jude Medical	St. Jude Medical Epic™ HF System
08-Jul-04	P030012	R2 Technologies, Inc.	ImageChecker® CT Lung CAD
26-Jul-04	H040002	Additional Technology	INTACS® Prescription Inserts
28-Jul-04	P010061	PhotoCure ASA	CureLight BroadBand (Model Curelight 01)
03-Aug-04	P030050	Dermik Laboratories	Sculptra
20-Aug-04	P030010	Siemens Medical Solutions USA, Inc.	Full Field Digital Mammography
24-Aug-04	H030009	Synthes (USA)	Vertical Expandable Prosthetic Titanium Rib (VEPTR)
30-Aug-04	P040012	Guidant Corp.	ACCULINK™ & RX ACCULINK™
10-Sep-04	P030028	Ophtec USA, Inc.	ARTISAN® (Models 206 & 204) and Verisyse™ (Models VRSM5US & VRSM6US) Phakic Intraocular Lens (PIOL)
29-Sep-04	P040029	Szabocsik and Associates	JSZ Orthokeratology

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 04. They represent significant medical breakthroughs because they are first-of-a-kind, e.g., they use a new technology or energy source, or they provide a major diagnostic or therapeutic advancement, such as reducing hospital stays, replacing the need for surgical intervention, reducing the time needed for a diagnostic determination, etc. The information for each device includes the trade name and/or classification name, firm, and date of approval or clearance.

- ODE PMA/HDE Approved Devices

Division of Cardiovascular Devices (DCD)

DeBakey VAD Child Ventricular Assist Device System by MicroMed Technologies, Inc. (February 25, 2004)

Acculink Carotid Stent system and RX Acculink Carotid Stent System (First of a kind carotid stent) by Guidant Corporation (August 30, 2004)

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

Morcher Capsular Tension Ring (CTR) Type: 14, 14A and 14C by Morcher GmbH (October 23, 2003)

Crystalens™ (Model AT-45) Accommodating Posterior chamber (PC) Intraocular lens (IOL) by Eyeonics Inc. (November 14, 2003)

Intacs Prescription Inserts for Keratoconus by Addition Technology (July 26, 2004)

ARTISAN® (Models 206 & 204) and Verisyse™ (Model VRSM5US &VRSM6US Phakic Intraocular Lens (PIOL) by Ophtec USA, Inc. (September 10, 2004)

JSZ Orthokeratology by Szabocsik and Associates (September 29, 2004)

Division of Reproductive, Abdominal and Radiological Devices (DRARD)

ImageChecker® CT Lung CAD by R2 Technologies, Inc. (July 8, 2004)

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

DCD

Accunet™ Embolic Protection Device by Guidant Corporation (August 31, 2004)

DGRND

KyphX HV-R Bone Cement by Kyphon, Inc. (April 1, 2004)

Stryker SpinePlex by Stryker Corp. (May 25, 2004)

MERCI Retriever by Concentric Medical, Inc. (August 11, 2004)

DOED

ProKera™ Ophthalmic Conformer by Bio-Tissue Inc. (December 12, 2003)

Reichert NCT (non-contact) Tonometer (January 16, 2004)

Zeiss Stratus OCT (optical coherence tomographer) with retinal neural layer and age-related macular degeneration database (April 20, 2004)

ODE Guidance Documents

In FY 04, ODE issued 30 guidance documents, 24 final and 6 draft, which are listed below. Of the 30, 8 are related to the implementation of MDUFMA, and 11 of the 30 are Special Controls guidance. These guidance documents and other previously issued guidance documents are available on the World Wide Web (CDRH homepage: http://www.fda.gov/cdrh) which provides easy access to the latest information and operating policies and procedures. They may also be obtained from the Division of Small Manufacturers International and Consumer Assistance (DSMICA, HFZ-200). To contact DSMICA, call 800-638-2041 or 301-443-6597; fax 301-443-8818; Email dsma@cdrh.fda.gov or write to DSMICA (HFZ-200, Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307.) Many guidance documents are also available through the CDRH Facts-On-Demand (faxback service at 800-899-0381 or 301-837-0111).

- ODE Final Guidance Documents Adopted

ODE MDUFMA Guidance Documents Adopted

FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Performance Assessment (October 8, 2003)

Premarket Approval Application Modular Review (November 3, 2003)

Guidance for Industry and FDA: User Fees and Refunds for Premarket Approval Applications (November 24, 2003)

Guidance for Industry and FDA: Bundling Multiple Devices or Multiple Indications in a Single Submission (November 26, 2003)

Guidance for Industry and FDA: Expedited Review of Premarket Submissions for Devices (November 26, 2003)

Premarket Assessment of Pediatric Medical Devices (May 14, 2004)

FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment (May 21, 2004)

User Fees and Refunds for Premarket Notification Submissions (510(k)s) (May 28, 2004)

Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reproceed Single-Use Medical Devices (June1, 2004)

ODE

Premarket Approval Application Modular Review (November 3, 2003)

Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures (July 6, 2004)

Third Party Review of Premarket Notifications (September 28, 2004)

DCD

Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm (October 28, 2003)

Clinical Study Designs for Percutaneous Catheter Ablation for Treatment of Atrial Fibrillation - Guidance for Industry and FDA Staff (January 9, 2004)

Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices- Draft Guidance for Industry and FDA Staff (February 25, 2004)

DAGID

Class II Special Controls Guidance Document – Dental Sonography and Jaw Tracking Devices – Guidance for Industry and FDA Staff (December 2, 2003)

Premarket Notification [510(k)] Submissions for Chemical Indicators – Guidance for Industry and FDA Staff (December 19, 2003)

Surgical Masks – Premarket Notification [510(k)] Submissions; Guidance for Industry and FDA (March 5, 2004).

Premarket Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove – Guidance for Industry and FDA Staff (April 13, 2004)

Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments (May 12, 2004).

Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices (June 1, 2004)

Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Dental Noble Metal Alloys (August 23, 2004; replaced Draft dated December 1, 2003)

Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Dental Base Metal Alloys (August 23, 2004 ; replaced Draft dated December 1, 2003)

DGRND

Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA (December 18, 2003)

Cyanoacrylate Tissue Adhesive for the Topical Approximation of Skin – Premarket Approval Applications (PMAs); Guidance for Industry and FDA (February 13, 2004)

Spinal System 510(k)s; Guidance for Industry and FDA (May 3, 2004)

DOED

Vocal Fold Medialization Devices - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff (February 13, 2004)

- ODE Draft Guidance Documents for Comment Purposes Only

Class II Special Controls Guidance Document: Dental Noble Metal Alloys (December 1, 2003)

Class II Special Controls Guidance Document: Dental Base Metal Alloys (December 1, 2003)

Saline, Silicone Gel, and Alternative Breast Implants (Level 1 draft to replace 1354 when final); Guidance for Industry and FDA (January 13, 2004)

Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices (Level 1 draft to replace 1151 when final); Guidance for Industry and FDA (February 25, 2004)

Class II Special Controls Guidance Document – External Penile Rigidity Device – Draft Guidance for Industry and FDA Staff (March 17, 2004)

Draft Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Dental Bone Grafting Material (June 30, 2004).

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. Historically, the ODE Annual Report has included combined data for both ODE and OIVD. However, the FY04 Annual Report includes predominately ODE data. The Tables and Figures here and the Tables in Part 7- OPERATIONAL STATISTICS now include two columns of information – OVID/ODE and ODE Only for FY04. 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 2004 with 314 employees. During the year, ODE lost 45 employees (16 scientific reviewers, 10 medical officers, 2 clerical and 2 program analyst/administrative officers, 4 interns, 11 contractors) through resignation, reassignment or retirement and added 41 new employees (15 scientific reviewers, 7 medical officers, 7 paid student interns and 12 contractors).

Workload

During FY 04, ODE received 8,436 major submissions. [See Table 1 for a breakdown of major submissions received.]

Table 1. Major Submissions Received
FY 95 – FY 04

TYPE OF SUBMISSION	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004 OIVD/ ODE	2004 ODE Only
Original PMAs	39	44	66	48	64	67	71	49	54	51	37
PMA Supplements	499	415	409	517	557	546	641	645	666	635	565
Original IDEs	214	253	297	322	304	311	284	312	242	226	222
IDE Amendments	210	219	223	226	275	240	206	252	216	167	167
IDE Supplements	3,171	3,189	3,776	4,277	4,127	4,388	4,811	4,724	4,415	4312	4298
510(k)s	6,056	5,297	5,049	4,623	4,458	4,202	4,248	4,320	4,247	3,635	3,110
Original HDE	0	0	4	8	12	11	5	5	10	9	9
HDE Supplements	0	0	0	0	4	10	16	16	29	29	28
Total	**10,189**	**9,417**	**9,824**	**10,021**	**9,801**	**9,775**	**10,282**	**10,323**	**9,879**	**9,064**	**8,436**

On the decision side, ODE completed the processing of 8,573 major submissions. [See Table 2 for major submissions completed.]

Table 2. Major Submissions Completed
FY 95 - FY 04

TYPE OF SUBMISSION	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004 OIVD/ ODE	2004 ODE Only
Original PMAs	27	43	48	40	36	42	53	41	31	39	30
PMA Supplements	435	462	401	421	440	474	442	533	494	466	424
Original IDEs	210	260	272	325	305	320	284	307	246	221	217
IDE Amendments	213	218	220	225	268	251	207	251	217	162	162
IDE Supplements	3,181	3,121	3,777	4,209	4,224	4,335	4,803	4,711	4,424	4348	4336
510(k)s	7,948	5,563	5,155	5,229	4,593	4,397	4,150	4,376	4,132	3,917	3,376
Original HDE	0	0	2	4	6	6	4	6	2	6	6
HDE Supplements	0	0	0	0	3	10	11	13	24	23	22
Total	**12,014**	**9,667**	**9,875**	**10,453**	**9,876**	**9,835**	**9,954**	**10,238**	**9,570**	**9,182**	**8,573**

Premarket Approval Applications (PMAs)

ODE received 37 original PMAs. The total number of PMAs in inventory (active and on hold) at the end of this fiscal year was 70. The number of active PMAs under review at the end of FY 04 was 27 and there were 43 on hold.

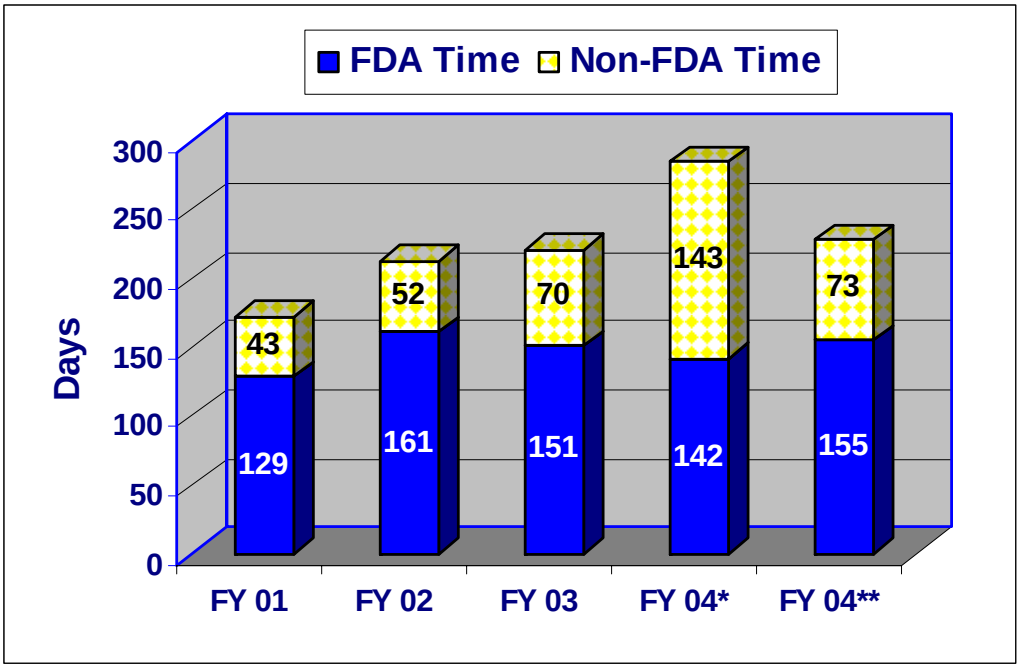
The total number of PMA actions was 198. These actions included 44 filing decisions, 102 scientific review decisions, and 52 approval/approvable/not approvable decisions.

The 52 original PMA decisions comprised 30 approved PMAs, 15 approvable PMAs, and 7 not approvable PMAs. Of the 30 approvals, 5 were expedited PMAs. See Part 2 (INDUSTRY INFORMATION) for a complete list of PMA approvals.

Average FDA review time for original PMAs reaching approval was 155 days in FY 04. The non-FDA component of review time was 73 days this fiscal year. Thus, the total average review time came to 228 days.

KEY PERFORMANCE INDICES

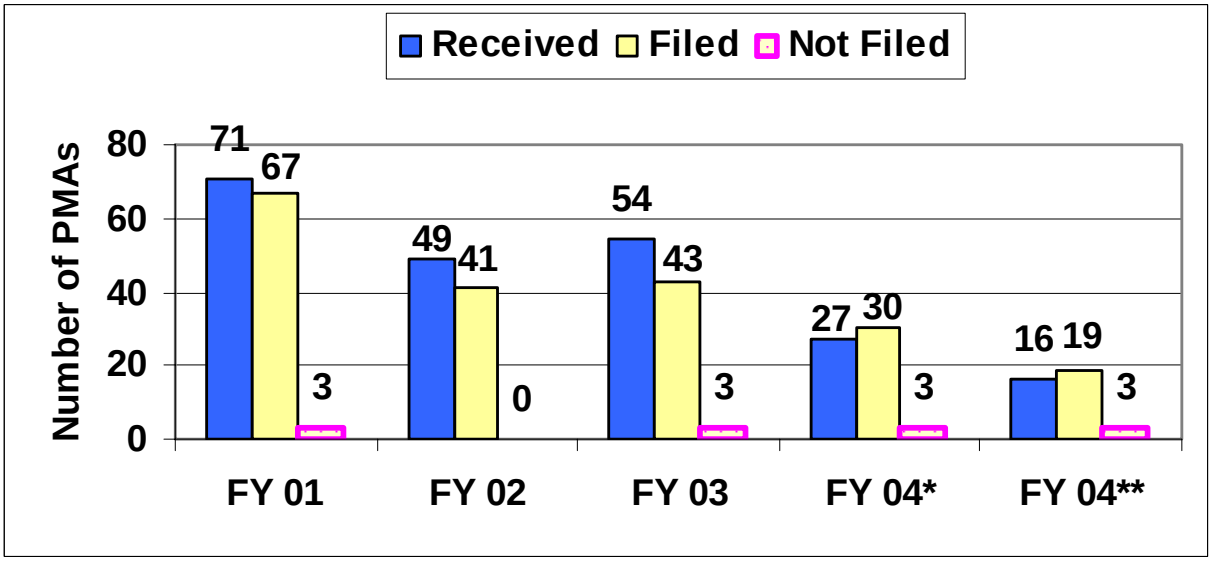
Figure 1. Average Review Time for PMA Decision Cohort Approvals



FY 04* ODE/OIVD
FY 04 ODE Only**

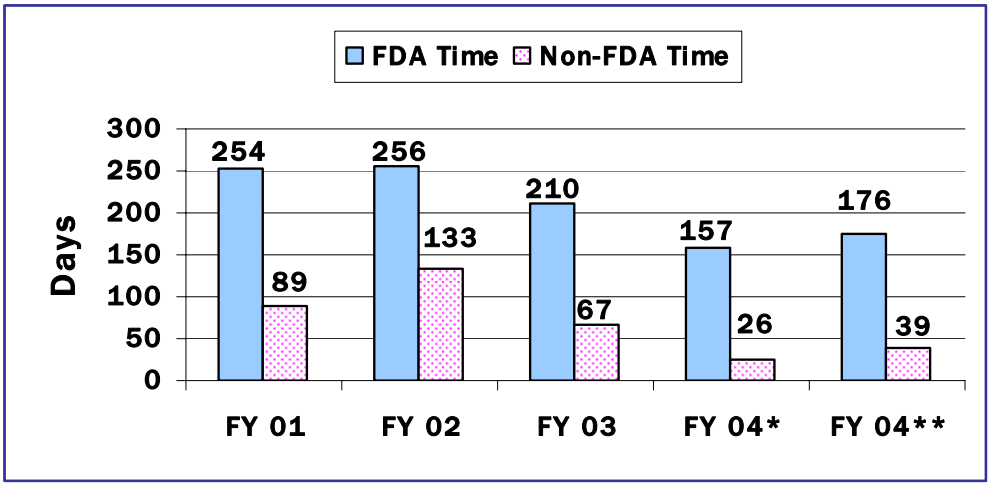
Of greater significance to industry is the total elapsed time from submission to decision. In FY 04, the total average elapsed time for PMA decision cohort performance was 436 days.

Figure 2. Original Receipt Cohort PMAs Received and Filed



*First six months
FY 04* ODE/OIVD
FY 04 ODE Only**

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



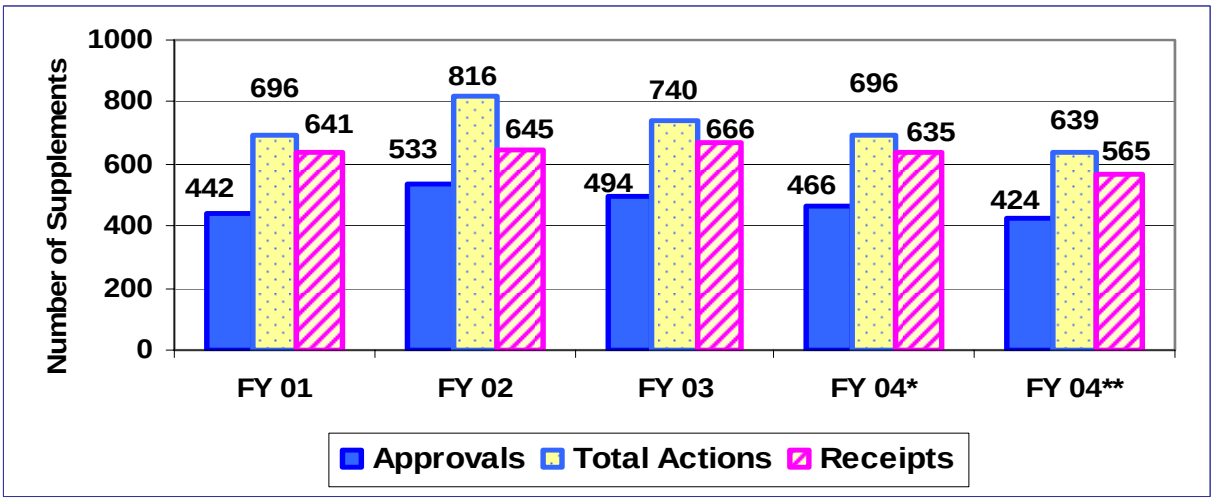
*First six months
FY 04* ODE/OIVD
FY 04 ODE Only**

For the first 6 months of FY 04 for PMA receipt cohort performance, the average FDA days from filing to first action was 113 days.

The average FDA (total) elapsed time to an approval or to a denial was 176(215) days in FY 04 (see Figure 3). The median FDA (total) elapsed time to an approval or denial decision was 177(220) days in FY 04. All of the statistics of the PMA receipt cohort for FY 04 indicated that we are making decisions faster.

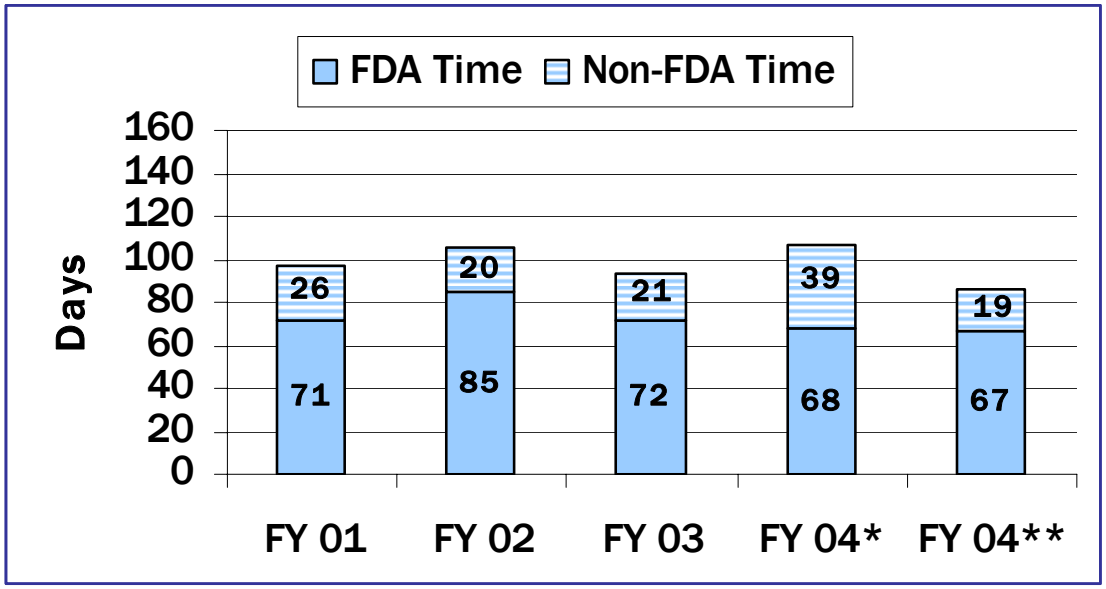
The number of PMA supplements received came to 565 in FY 04. There were 639 PMA supplement actions. These actions included 7 panel track PMA supplement filing decisions, 81 scientific review decisions, and 551 approval decisions (see Figure 4).

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



For PMA supplements reaching final action, the average total review time was 86 days in FY 04 (see Figure 5), and the average total elapsed time was 106 days.

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



There were 4 PMA supplements active and overdue at the end of this fiscal year. The number of active supplements totaled 106 in FY 04, and the number of supplements on hold came to 94.

For the first 6 months of FY 04 for PMA supplements receipt cohort performance, the first action and final action are as follows. The average FDA days from filing to first action was 55 days. The average FDA (total) elapsed time to an approval or denial was 55(62). The median FDA (total) elapsed time to an approval or denial came to 30(30) 30(30) days in FY 04.

Real-Time Review of PMA Supplements

A total of 178 requests were received and processed for real time PMA supplements in FY 04 which represents 31% of all supplements received. Of those submissions, 147 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 (60%) followed by DOED (16%), DGRND (14%), DRARD (7%), and DAGID (3%). Overall, average review time from receipt to final approval was 53 days.

Product Development Protocols (PDPs)

One original PDP was approved in FY 04. Three routine PDP supplements and six "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 04 ODE received a total of 21 PMA shells and 65 modules. A total of 4 modules were found to be acceptable while 10 received deficiency letters. Seven modules were rolled into PMA review during FY 04 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 9 original HDEs. The total number of original HDE actions 38 in FY 0 04. These actions included 8 filing decisions, 18 review determinations, 5 approval decisions and 5 other final decisions.

A total of 7 first actions were made this fiscal year. The average time from filing to first action was 52 days in FY 04.

One hundred percent of the first actions made in FY 04 occurred within 75 days.

In FY 04, the average elapsed time (from filing to final approval) for original HDEs was 287 days. The average FDA time was 195 days. The average non-FDA time was 92 days.

The total number of original HDEs in inventory (active and on hold) at the end of this fiscal year was 8. Of these, 4 were under review and 3 were on hold. There was 1 active HDE that was overdue at the end of the fiscal year.

The number of HDE supplements received was 28 in FY 04. There were 39 HDE supplement actions in FY 04. These actions included 22 approvals, 6 approvable, and 3 not approvable decisions.

A total of 37 first actions for HDE supplements were made this fiscal year. The average time from filing to first action was 36 days in FY 04. Forty-nine percent of the first actions were made within 75 days.

The average elapsed time (from filing to final approval) for HDE supplements was 90 days in FY 04. The average FDA time was 61 days in FY 04. Non-FDA time was 29 days in FY 04.

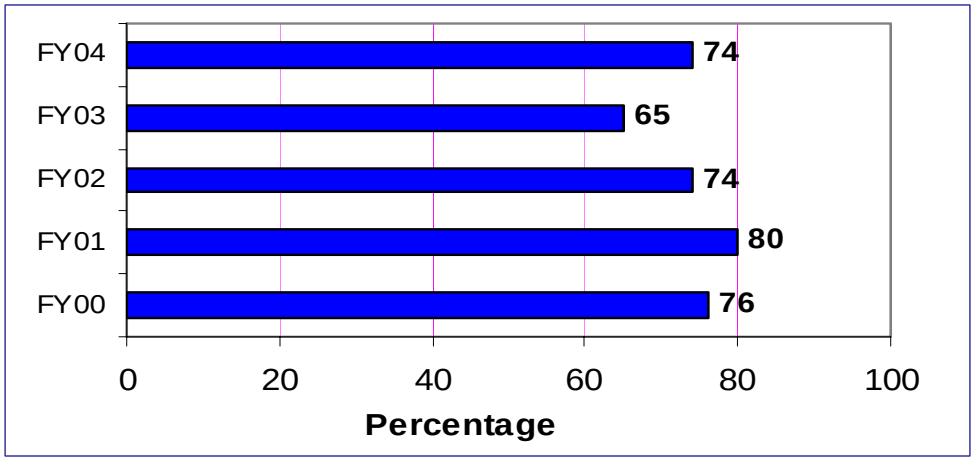
The number of HDE supplements in inventory (active and on hold) at the end of this fiscal year was 11. Of these, 7 were under review and 4 were on hold. There were no active HDE supplements that were overdue at the end of the fiscal year.

Investigational Device Exemptions (IDE)

During FY 04, ODE reviewed 378 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 222 original IDEs. There were 217 decisions made on original IDEs. One hundred percent of all original IDE decisions were issued within 30 days in FY 04. 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 original IDEs which were complete enough to support substantive review, the percentage of IDEs approved on the first review cycle was to 74% in FY 04.

During this fiscal year, 167 IDE amendments were received. Decisions were made on 162 amendments: 61 approvals (38%); 27 disapprovals (17%); and 74 other administrative actions (46%). One hundred percent of these decisions were made within 30 days.

It took an average total time of 161 days to approve IDEs that were initially disapproved. This average approval time consisted of 61 days for FDA time, the same as last year, and 100 days for non-FDA time.

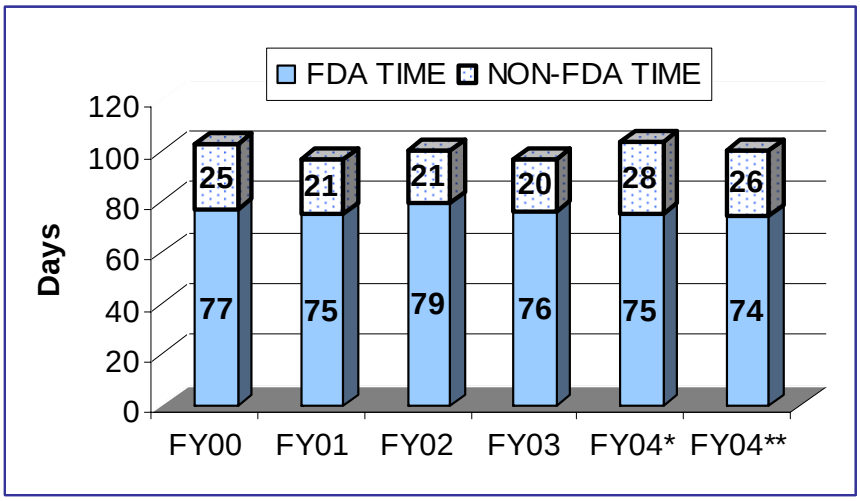
ODE received 4,298 IDE supplements during FY 04. There were no overdue supplements at the end of the year, and the percentage of supplements reviewed within the 30-day statutory timeframe was 100% in FY 04. The average review time for IDE supplements was 19 days.

Premarket Notification (510(k)s)

ODE received 3,110 original 510(k)s, as well as 1,787 510(k) supplements (responses to hold letters, the receipt of which restart the 90-day review clock), and 1,408 510(k) amendments (additional information received while the 510(k) is under review, the receipt of which does not affect the review clock). One 510(k) was granted expedited status in FY 04.

The total average review time was 100 days in FY 04, and the average FDA review time was 74 days. The median review time, i.e., the time it took to review 50% of the 510(k)s, was 70 days in FY 04.

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

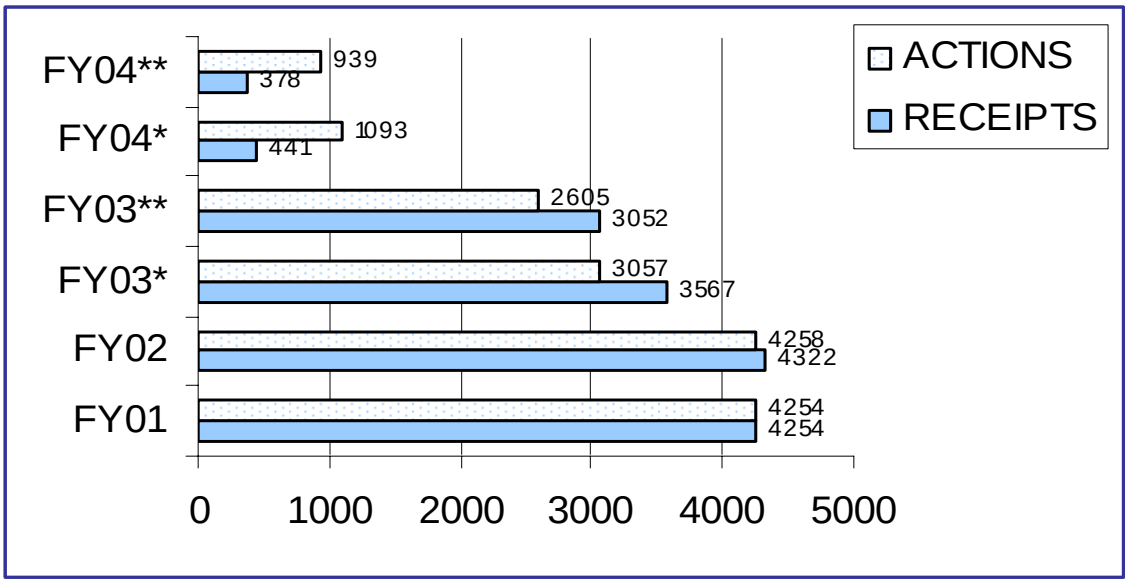


*ODE Only
**ODE/OIVD

There were 1,391 510(k)s in inventory (those under active review or on hold) at the end of this fiscal year. The number on hold at the end of FY 04 was 376. Most important, for the eighth consecutive fiscal year there were no 510(k)s active and overdue at the end of the reporting period.

For the first 9 months of FY 04 for receipt cohort performance, the FDA time from receipt to final decision was 57 days ODE/OIVD and 58 days for ODE only.

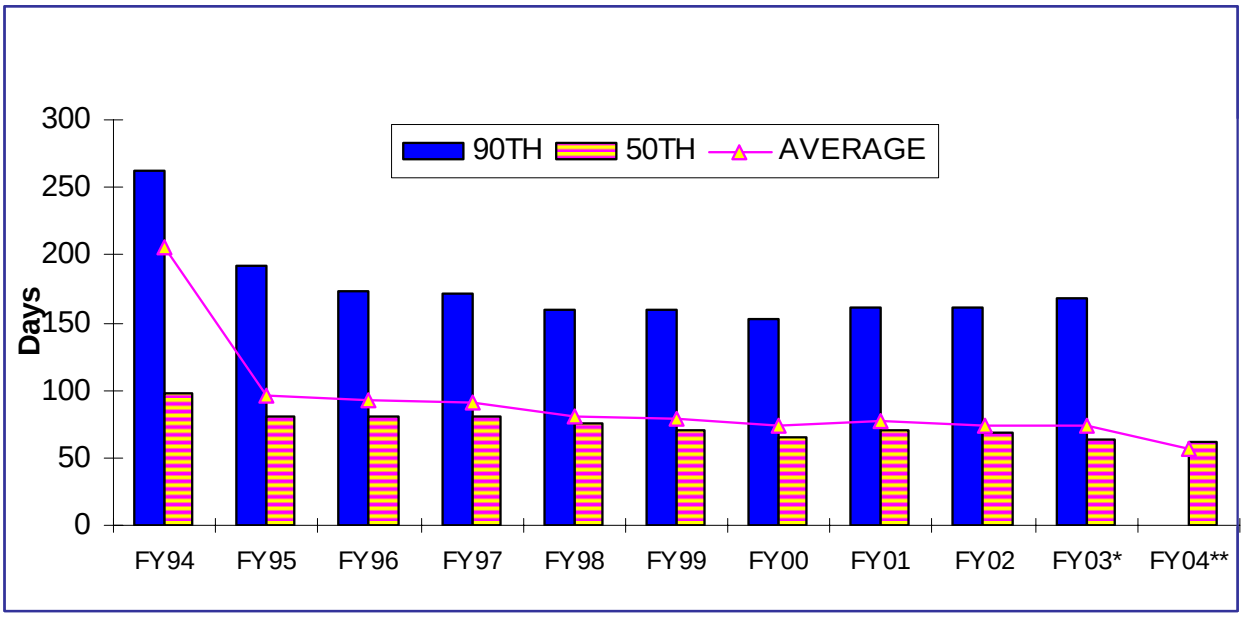
Figure 8. Receipts and Actions for 510(k) Receipt Cohorts+ - ODE/OIVD



+ CutOff Date of 9/30/04 all receipt cohorts.
*ODE/OIVD
**ODE Only

For the first 9 months of FY 04 for receipt cohort performance, the total time from receipt to final decision decreased to 65 days ODE/OIVD and 65 days for ODE only.

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



*Cut Off Date as of 9/30/04 for all receipt cohorts.
**For the first 9 months of FY 04. 90th percentile data not available for FY 04.

Third-Party Review of 510(k)s

During FY 04, ODE and OIVD received 255 510(k)s (242 and 13, respectively) reviewed by third-party organizations under the Accredited Persons provisions (section 523) of the Federal Food, Drug, and Cosmetic Act. This was a 34 percent increase over the 190 submissions received last fiscal year, and more than twice the 127 submissions received in FY 02. The increase may be attributable, at least in part, to FDA's implementation of MDUFMA's user fee provisions during FY 2003 that require applicants to pay a fee when submitting 510(k)s without a third-party review.

ODE and OIVD made final decisions on 244 "third party" 510(k)s in FY 04 (231 and 13, respectively), an increase from the 169 final decisions in FY 03.

CDRH took steps during FY 04 to improve the quality and consistency of third party reviews and facilitate ODE's and OIVD's timely action on these submissions. In March 2004, CDRH initiated quarterly telephone conferences with all third parties to provide a routine forum for discussing issues and answering questions. On September 28, 2004, the Center issued an updated guidance document on conducting and documenting third party reviews (see http://www.fda.gov/cdrh/ode/guidance/2237.pdf). The Center also arranged training sessions for ODE/OIVD staff and third party reviewers, scheduled for October 22, 2004 in Rockville, Maryland and October 26-27, 2004 in Gaithersburg, Maryland, respectively.

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

Special 510(k)s

From October 1, 2003 to September 30, 2004 ODE received 720 Special 510(k)s out of the 3,110 total number of 510(k)s received. During the fiscal year 748 have received final decisions (720 were found substantially equivalent, 4 were found not substantially equivalent, and the remaining 24 had other decisions such as withdrawn or deleted) with the average FDA review time of 30 days and the average total time of 40 days.

Abbreviated 510(k)s

During this fiscal year, ODE received 110 *Abbreviated* 510(k)s out of the 3,110 total number of 510(k)s received. One hundred twenty-seven received final decisions (101 substantially equivalent, 6 not substantially equivalent, and 20 other decisions) with a FDA average review time of 86 days and total time of 119 days.

ODE Device Guidance Documents

By the end of the fiscal year, ODE issued 26 final guidance documents and issued another 56 drafts for comment. Of the 30 total, 8 were specifically related to MDUFMA. ODE guidance documents issued this year are listed under Part 2 – Industry Information.

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

Guidance Development Templates

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

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

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

Risk Management in Guidance Development Templates

Guidance is an effective risk management tool and a critical element of the Commissioner's Strategic Plan. Moreover, clear, accurate scientific communication in guidance reduces the burden on both industry and FDA. The opportunity to incorporate FDA recognized standards in guidance provides industry and FDA with testing methods and acceptance criteria vetted by experts who represent the international device community, further ensuring clear communication and reducing the burden of regulation. All of ODE's guidance development templates focus on addressing the risks to health associated with the use of devices and the measures FDA has identified to

mitigate those risks, measures that follow the systems theory approach, by showing how quality systems requirements, premarket review, and postmarket oversight serve together as a system of regulatory controls to assure the safety and effectiveness of devices marketed in the U.S.

Significant Medical Device Approvals

During FY 04, ODE approved 8 PMAs and cleared 7 510(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 March 17, 2004 to classify external penile rigidity devices intended to create or maintain sufficient penile rigidity for sexual intercourse into class II. Also, FDA is giving notice of its intent to exempt this type of device from premarket notification.

Final Classification Actions

- Published a final rule classifying silicone sheeting intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars into class I (exempt). [Effective August 9, 2004]

- Published a final rule requiring the filing of a premarket approval application or a notice of completion of a product development protocol for three class III preamedment devices: Indwelling blood oxyhemoglobin concentration analyzer, cardiopulmonary bypass pulsatile flow generator, and the ocular plethysmograph. [Effective June 23, 2004].

- Published a final rule classifying Human Dura Mater intended to repair defects in human dura mater into class II. [Effective January 20, 2004].

- Published a final rule classifying the dental sonography device into class I, when it is used to monitor temporomandibular joint sounds, and into class II, when it is used to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. [Effective January 2, 2004].

Proposed Reclassification Actions

- Published a proposed rule in the Federal Register on February 25, 2004 to reclassify the Vascular Embolization Device and the Neurological Embolization Device into Class II.

- Published a proposed rule in the Federal Register on June 30, 2004 to reclassify tricalcium phosphate (TCP) granules for dental bone repair from class III to class II; classify into class II all other bone grafting material for dental indications, except those that contain a drug or biologic components; and revise the classification name and identification of the device. Bone grafting materials that contain a drug or biologic component would remain in class III.

Final Reclassification Actions

- Published a final rule in the Federal Register on May 12, 2004 to reclassify Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments from class III to class II [Effective June 11, 2004].

- Published a final rule in the Federal Register on October 28, 2003 to reclassify arrhythmia detector and alarm devices from class III to class II. [Effective November 28, 2003].

Automatic Evaluation of Class III Designation

- Issued an order on June 25, 2004 classifying Celleration MIST Therapy System into class II 878.4410.

515(b)

- Published a proposed rule on March 5, 2004 for the Effective Date of the Requirement for Premarket Approval of the Hip Joint Metal/Polymer or Ceramic/polymer Semi-constrained, Resurfacing Cemented Prosthesis; Opportunity to request a change in classification.

513(g) Submissions

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

During this fiscal year, ODE received 240 513(g) requests for information. ODE has responded to 187 of these requests, while reviews of the remaining 53 requests are ongoing.

Part 4 – Major Program Initiatives

Division Tracking System (DTS)

The Division Tracking System (DTS) is a web-based tracking system which allows easy entry and access to file information and serves as a mechanism to evaluate MDUFMA performance. It is designed to track the progress of a document through the review process and thus assist the Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostic Device Evaluation and Safety (OVID) in managing documents and review projects in order to measure, monitor and/or meet MDUFMA, office, division, or branch goals. The system allows performance of the same functions as the earlier document tracking systems but provides user the abilities such as generating of individual reports, organizing, searching and viewing files. The new system provides additional capabilities in a web-based environment. It is designed to supplement, not replace, the data already existing in the POS databases. Additionally, the current Division Tracking System (DTS) allows the OVID to measure, monitor and/or meet Clinical Laboratory Improvement Amendments (CLIA) issues and Office of Combination Products (OCP) to track Request For Designation (RFD) documents.

ODE/DRARD/Epi Pilot Project

As part of ODE's effort to formalize Total Product Life Cycle precepts within the premarket review process, the Division of Reproductive, Abdominal, and Radiological Devices (DRARD) continued their pilot cooperative project with the Epidemiology Branch (EB) of the Office of Surveillance and Biometrics. The purpose of the project is 1) to determine when and how the EB could best provide appropriate input/recommendations to DRARD regarding potential postmarket investigations and 2) to initiate, and later evaluate, product-specific Postmarket Plans. The epidemiologists continue to participate in the review of PMAs being evaluated by DRARD. Two of the PMAs that were approved during the year had post approval studies. In both cases the epidemiology reviewer played a large role in the study design. Both groups believed that the involvement of the EB in the PMA review enhanced the review process. All participants believed that early involvement was the best approach, with "early" now being defined as beginning at the time of the filing meeting. Both groups believed that there was not enough experience gained in the first two years of the pilot and that continuing the pilot would allow for further refinement of the process. Therefore the decision was made to continue the pilot project over the next year.

30-Day Notice Program

In accordance with section 515(d)(6) of the Federal Food, Drug, and Cosmetic Act, PMA applicants are required to submit 30 day Notices for changes to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of the

device. Historically, 30-day notices have been jointly reviewed by both ODE and OC. The official letter accepting/rejecting the Notices was signed by ODE, because the OC did not have the regulatory authority to sign official PMA letters. Because of this joint effort, there is a delay in sending the decision letter to the PMA applicant. To make this process more efficient, the regulation was revised to provide OC division directors the authority to sign 30 day Notices/135-day Supplements. Since the expertise for reviewing manufacturing information and determining compliance with QSR belongs to OC, it is most appropriate to have OC assume full responsibility for conducting these reviews, making final decisions, and signing off on 30-Day Notices and 135-Day PMA/HDE/PDP Supplements for Manufacturing Method or Process Changes.

Part 5 – Other Program Activities

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

During FY 2004, ODE continued efforts to implement the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), P.L. 107-250.

ODE hired 15 MDUFMA employees in FY 2004: 7 engineers, 5 medical officers, 1 nurse, 1 physicist and 1 microbiologist; and expanded the use of contractors to allow FDA to meet review workloads, strengthen expertise, and improve IT infrastructure. ODE accelerated training of new and existing staff of the new guidance required to implement MDUFMA, and developed training plans to increase clinical and technical training. ODE issued 8 MDUFMA guidances, 6 were level one and 2 were level two-- the 2 level two's were modular and expedited. ODE met all the MDUFMA statutory deadlines for FY 2004 and maintained or improved device review performance in areas not covered by official performance goals. ODE also continued outreach efforts to stakeholders explaining the new requirements and provisions of MDUFMA. This was accomplished through Internet sites to provide MDUFMA information, letters to consumer and trade organizations and manufacturers, a Public Docket, briefings, presentations, and direct responses to phone calls and letters.

The CDRH annual report and the MDUFMA web site (www.fda.gov/cdrh/mdufma) provide more information on performance goals, presentations and reports, guidance documents, and useful reference materials.

Bioterrorism Preparedness

ODE continues to be involved in several resource-intense initiatives related to national bioterrorism preparedness and response. ODE established liaisons and continues to collaborate with other government agencies and the military to prepare for and assume regulatory responsibilities applicable to 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.

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. The final document was released on the internet on September 30, 2002 and in the

October 4, 2002 Federal Register (67 FR62252). The guidance may be found on the Center's website at www.fda.gov/cdrh/ode/guidance/1332.html.

Study Determination Inquiries

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

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

When responding to these inquiries, there are three possible responses: the research is exempt from the IDE regulation; the abbreviated IDE requirements must be met (nonsignificant risk [NSR] study); or the full requirements of the IDE regulation must be met, that is, an IDE application must be submitted to FDA (significant risk [SR] study). In FY 04 ODE received 65 inquires. Of the 65 inquires, there were 11 SR determinations, 30 NSR determinations, 18 exempt determinations, and 3 inquires still under review. One was determined to have CDER jurisdiction, and two others were not pursued after we requested additional information.

Significant Jurisdictional Issues

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

In FY 04 CDRH participated in the review of 39 out of 51 RFD's received by the FDA's Ombudsman's Office, in addition to completing the reviews of six (6) RFDs received in FY

03. Two (2) RFDs did not require CDRH involvement, two (2) were withdrawn before we started or completed the review of those RFDs and eight (8) RFD's were never filed and sent to the Centers by OCP. The reviews of the new requests were assigned to the ODE Divisions as follows: DGRND was assigned thirteen (13); DAGID was assigned twelve (12); DRARD was assigned eight (8); DCD was assigned four (4); DOED reviewed three (3) and the remaining RFD was assigned to OIVD to review. The number of Division RFD reviews exceeded the total number of RFDs as several required multiple Division review.

Of the 45 RFD's [39 assigned in FY 04 and the 6 carry over from FY 03] which CDRH completed reviews during FY 04:

- CDRH was assigned the lead center in 25 of those requests
- CDER was assigned lead center in 9

- CBER was designated lead in 4 RFDs
- Two (2) were assigned to Dual (CDRH and CDER) Center Leads

Five (5) RFDs were not due for completion until FY 05.

Transmissible Spongiform Encephalopathy (TSE)

ODE continues to be actively involved in agency and CDRH TSE activities. ODE in coordination with other CDRH offices, CBER, CDER and CFSAN has worked to develop regulations to add further safeguards in the selection of bovine materials used in medical products. Along with CDRH and these other centers, ODE has participated in the Center for Biologics February and July 2004 FDA CBER TSE Advisory Committee (TSEAC) meetings. The ODE presentation for CDRH at the February 2004 TSEAC meeting provided an update that there were no medical devices that have been cleared or approved that claim the ability to remove or detect TSE contamination.

ODE has held been active in the monthly CDRH TSE Working Group meetings where CDRH meetings, issues and concerns are discussed to maintain communication among the center experts.

Advisory Panel Activities

The Center's Medical Devices Advisory Committee (MDAC) with its 18 panels provides clinical and scientific advice to FDA in a number of areas fundamental to the regulation of medical devices. The primary areas of activity are: (1) review and recommendations on premarket submissions, primarily Premarket Approval Applications (PMAs), and 510(k)s, (2) classification and reclassification of medical devices based on risk to patients, (3) advice on guidance documents that provide industry and FDA staff with expectations for

studies and data for premarket reviews, and (4) input on new issues or questions concerning the determination of the safety or effectiveness of medical devices.

In FY04, ODE held twenty-one panel meetings. These panels reviewed and made recommendations on twenty PMAs, one 510(k), two reclassification petitions, and three general issues. In FY04 there were 20 training sessions for new panel members and consultants. The panels reviewed PMAs for significant device breakthrough technologies such as a computed tomography (CT) computer aided detector (CAD) device for detecting solid pulmonary nodules, a magnetic resonance imaging (MRI) guided uterine fibroid focused ultrasound ablation system and a total artificial heart for use as a bridge to transplant for patients in imminent risk of death.

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

The MDAC panels are key to ensuring that the agency has access to the nation's esteemed medical and scientific 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 ongoing medical device review process.

ODE Integrity Program

During this fiscal year, ODE/OIVD considered about 58 cases concerning the integrity of data submitted to the agency in premarket applications. Under the Application Integrity Program (AIP), three firms were placed on the AIP list and AIP restrictions applied against these firms. An Integrity Hold was placed on three firms' applications during FY 04, and we removed one application from Integrity Hold.

ODE handled 25 instances related to questions arising under the standards of conduct for employees. During FY 04, as in years past, the ODE/OIVD staff received several unsolicited gifts from the regulated industry. Both the offering of gifts and their acceptance in general, are prohibited under applicable laws and regulations. The regulated industry, their agents and representatives should not send gifts to staff members. See Standards of Ethical Conduct for Employees of the Executive Branch on the internet at http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/reference/rfsoc_99.pdf.

Part 6 - Program Support

Freedom of Information Requests

ODE staff received 972 FOI requests during FY04, an increase from 512 in the last fiscal year. During FY04, the number of FOI requests closed was 547 compared to 836 in FY03. The total number of FOI requests pending in ODE at the end of FY04 is 587 compared to 207 in FY03.

Congressional Inquiries

Staff from ODE responded to Congressional inquiries and participated in briefings on the following topics -- breast implants, electromagnetic treatment devices, automatic external defibrillators, menstrual cups, accreditation of radiology facilities, microderm abrasion machine, liquid oxygen, x-ray screening for asbestos, motor cortex, chair lift, and condoms. ODE also participated in hearings of Congressional committees and briefings of Congressional staff during FY 04. These topics dealt with FDA's budget and labeling of condoms.

Publications

During FY04, ODE staff authored 19 manuscripts for publication in professional and scientific journals and delivered 105 presentations at professional, scientific and trade association meetings. See Appendix B for a bibliography of publications.

ODE Vendor Day

On October 23, 2003, ODE sponsored a vendor day on heart valve devices. Companies represented included Metronic, St. Jude Medical, Edwards Lifesciences, and Centerpulse Cardiac Division/Carbomedics. Several vendor days are being planned for FY05.

Site Visits

In FY04, 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 firms and/or hospitals were visited by 128 scientific reviewers to learn about such things as hearing aids, lasers or aesthetic procedures, heart failure clinical procedures, endosseous implants, anesthesia ventilators, vaporizers and nitric oxide delivery devices, antimicrobial coating applications, tissue heart valves, heart valves, bone void filler/bone cements,

retinal implants, aberrometry and visual optics, thoracic stent-grafts, intraocular lenses and various ophthalmic implants, 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's effort to increase the hiring of minorities and those with a disability, ODE participated in the 2004 Marriott Bridges Students with a Disabilities Program. In addition, ODE participated in several other recruiting fairs including: the 2004 Miami Diversity Career Fair, 2004 Blacks in Government Career Fair and the 2004 Hispanic Reporter's Hispanic Career Fair, just to name a few.

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

In an effort to enhance and expand resources for the Office of Device Evaluation, the Program Management Office continues to use a variety of methods through the **OTHER** initiative. Some of the OTHER programs that were utilized in FY 2004 include:

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

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 95 hours of training per employee in 2004. 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

Electronic Submissions

In FY 04, ODE received 48 complete electronic copies of submissions for PMAs, IDEs, Pre-IDEs and 510(k)s from 16 different sponsors in addition to the paper submission. These numbers show a decrease from FY 03 when 97 complete submissions were received from 25 different sponsors. Prior contact with an ODE division is still requested before developing and sending an electronic copy. Electronic copies enhance the efficiency of the review process, especially when several CDRH Offices are involved in the review of the submission. Instructions for submitting submissions in electronic form can be found on the CDRH home page at the address http://www.fda.gov/cdrh/elecsub.html.

Medical Device Web Home Page

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

Video Conferencing

CDRH 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 FY 04, ODE held 5 video conferences with industry, Federal agencies and with the US Army.

Computer Tracking Systems

The primary work performed in FY 2004 was the development of the new Division Tracking System (DTS). This new web-based application was designed to provide more effective tracking of premarket submissions. The project deliverables included

prototyping sessions, data entry revisions, data migration, user training, standard and user-generated reports, a user's guide and documentation. Also, there were various levels of effort to integrate DTS with other Center applications and this effort will continue in FY 2005. In addition to this application, considerable work was done in reconciling 510k and PMA user fee data.

Office Automation

ODE installed medical/pharmaceutical/dental/biotech spell checking software on all of the ODE computers to assist in the preparation of review-related documents. ODE continued to install docking laptops to enable reviewers to use the same computer at work and at home with all files available at both locations. In addition, ODE increased the number of users working from home and continued to provide training and equipment for offsite access to the FDA network.

Image2000

The CDRH system for storing electronic copies of device application submissions was upgraded to provide additional capabilities for ODE reviewers. The new system now stores documents in Portable Document Format (PDF), the Agency's standard, and allows for full text searching, for copying or saving documents and for printing all or part of the submission. The system has been so well received that in FY04 ODE began the task of scanning over 2200 boxes of past IDE and PMA paper submissions currently stored at an offsite warehouse into the system making the data electronic, searchable and easily retrievable from the reviewers desktop.

Electronic Shared Workplace

In FY04, ODE piloted the use of web-based software to facilitate communication and interactions among team members in the review of PMAs. The software was used with all new PMAs and PMA supplements for specific branches in ODE and with other specific PMAs from non-pilot branches. A software template and the rules for using the software were developed by a cross-center team including representatives from ODE and several of the offices involved in the review of PMAs. The results of the pilot will be assessed to determine whether the template will be rolled out CDRH-wide for PMA reviews. The software is also used by groups within ODE for collaboration, document creation, and document posting in a shared work space.

Processing Premarket Applications

Since the passage of FDAMA and MDUFMA, there is a definite need to optimize and modernize CDRH premarket administrative processes and the supporting IT architecture

and systems. A Center-wide group is identifying current inefficiencies in the processing of Premarket Applications and will develop improved procedures that will be phased in on a prioritized basis.

Consumer Information

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

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

Part 7 – Operational Statistics

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

Table 3. PMA/HDE/IDE/510(k) Submissions Received FY 01 - FY 04

TYPE OF SUBMISSION	NUMBER RECEIVED				
	FY01	FY02	FY03	FY04 OIVD/ODE	FY04 ODE Only
Premarket Approval (PMAs)					
Original Applications	71	49	54	51	37
Amendments	746	748	564	611	545
Supplements	641	645	669	635	565
Amendments to Supplements	920	860	817	689	635
Reports for Original Applications	494	583	703	743	681
Reports for Supplements	0	1	0	1	0
Master Files	37	44	44	57	57
PMA Subtotal	**2,909**	**2,930**	**2,851**	**2,792**	**2,525**
Humanitarian Device Exemptions (HDEs)					
Original Applications	5	5	10	9	9
Amendments	62	53	41	53	53
Supplements	16	16	29	29	28
Amendments to Supplements	8	20	25	18	17
Reports for Original Applications	24	29	37	16	16
Reports for Supplements	0	0	0	0	0
HDE Subtotal	**115**	**93**	**142**	**125**	**123**
Investigational Device Exemptions (IDEs)					
Original Applications	284	312	242	226	222
Amendments	206	252	216	167	167
Supplements	4,811	4,724	4,414	4,312	4,298
IDE Subtotal	**5,301**	**5,288**	**4,872**	**4,705**	**4,687**
Premarket Notification (510(k)s)					
Original Notifications	4,248	4,320	4,247	3,635	3, 110
Supplements	1,579	1,780	1,856	2,041	1,787
Amendments	2,620	2,385	1,690	1,603	1,408
510(k) Subtotal	**8,447**	**8,485**	**7,793**	**7,279**	**6,305**
PMA/HDE/IDE/510(k) Total	**16,772**	**16,796**	**15,658**	**14,558**	**13,640**

Table 4. Original PMA Decision Cohort Performance FY 01- FY 04

	FY 01	FY 02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Number Received	71	49	54	51	37
PMA Action					
Filing Decisions					
Filed	62	44	43	55	40
Not Filed	5	3	11	4	4
Others	0	0	0	0	0
Filing Decisions Subtotal	**67**	**47**	**54**	**59**	**44**
Scientific Review Decisions					
Major Deficiencies	35	29	29	46	32
Minor Deficiencies	4	2	1	0	0
Other[a]	94	91	57	79	70
Scientific Review Decisions Subtotal	**133**	**122**	**87**	**125**	**102**
Approval Decisions					
Approvals	53	41	31	39	30
Approvable	19	17	16	15	15
Not Approvable	10	10	10	8	7
Denials	0	0	0	0	0
Approval Decision Subtotal	**82**	**68**	**57**	**62**	**52**
Total PMA Actions	**282**	**237**	**198**	**246**	**198**
Average Review Time (Days) for Approvals[b]					
FDA	129	161	151	142	155
Non-FDA	43	52	70	143	73
Total	**172**	**213**	**221**	**285**	**228**
Average Elapsed Time (Days) for Approvals[c]					
FDA	257	260	246	260	266
Non-FDA	154	104	113	243	170
Total	**411**	**364**	**359**	**503**	**436**
Number under Review at End of Period[d]					
Active[e]	56	45	38	29	27
(Active and Overdue)	(16)	(10)	(5)	(2)	(2)
On Hold[f]	39	31	48	54	43
Total	**95**	**76**	**86**	**83**	**70**

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 01– FY 04

	FY01	FY02	FY03	FY04 OIVD/ODE	FY04 ODE Only
Original PMAs Filed					
PMAs	59	32	40	21	11
Expedited PMAs	8	9	3	9	8
Total	**67**	**41**	**43**	**30**	**19**
Filing Decisions[a]					
Filed	67	41	43	30	19
Not Filed	3	0	3	3	3
Number (%) of Filing/Not Filing Decisions within 45 Days	47(66)	31(76)	32(71)	25(76)	16(73)
Average Days/Cycle	44	41	42	38	39
Final Actions[b]					
Approvals	48	31	26	6	4
Denials	0	0	0	0	0
Other[c]	17	11	6	0	0
Total	**65**	**42**	**32**	**6**	**4**
Filing to First Action Excluding withdrawals, conversions, etc.[d]					
Number Received and Filed	67	41	43	30	19
Number of First Actions	67	41	43	30	19
Average FDA Days	132	136	126	110	113
Median FDA Days	133	143	129	110	111
Number (%) of First Actions with 180 Days	65(97)	38(93)	42(98)	30(100)	19(100)
Filing to First Action Including withdrawals, conversions, etc.[e]					
Number Received and Filed	67	41	43	30	19
Number of First Actions	67	41	43	30	19
Average FDA Days	132	136	126	110	113
Median FDA Days	133	143	129	110	111
Number (%) of First Actions with 180 Days	65(97)	38(93)	42(98)	30(100)	19(100)
Filing to Final Action Excluding withdrawals, conversions, etc.[f]					
Number Received and Filed	67	41	43	30	19
Number of Final Actions	49	31	26	6	4
Average FDA (Total) Elapsed Time	254(343)	256(389)	210(277)	157(183)	176(215)
Median FDA (Total) Elapsed Time	193(263)	243(341)	195(262)	172(181)	177(220)
Number (%) of Final Actions with 180 FDA Days	19(39)	11(35)	11(42)	5(83)	3(75)
Number (%) of Final Actions with 180 Total Days	11(22)	4(13)	5(19)	3(50)	1(25)
Filing to Final Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	67	41	43	30	19
Number of Final Actions	61	36	30	6	4
Average FDA (Total) Elapsed Time	240(400)	250(407)	202(296)	157(183)	176(215)
Median FDA (Total) Elapsed Time	191(316)	237(375)	183(280)	172(181)	177(220)
Number (%) of Final Actions with 180 FDA Days	26(43)	14(39)	15(50)	5(83)	3(75)
Number (%) of Final Actions with 180 Total Days	11(18)	4(11)	5(17)	3(50)	1(25)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[b]	1.7	1.8	1.5	1.3	1.5

Continued on next page.)

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

(Continued from previous page.)

	FY01	FY02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Percentile FDA Days from Filing to First Action[d]					
25th	105	108	94	89	84
50th (Median)	133	143	129	110	111
75th	176	176	174	145	157
90th	179	180	178	176	178
Percentile FDA Days from Filing to First Action[e]					
25th	105	108	94	89	84
50th (Median)	133	143	129	110	111
75th	176	176	174	145	157
90th	179	180	178	176	178
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	177(180)	178(270)	174(205)	142(142)	172(181)
50th (Median)	193(263)	243(341)	195(262)	172(181)	177(220)
75th	287(379)	335(435)	267(321)	177(245)	179(248)
90th	378(733)	381(699)	302(437)	181(251)	181(251)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	177(198)	178(277)	172(250)	142(142)	172(181)
50th (Median)	191(316)	237(375)	183(280)	172(181)	177(220)
75th	271(469)	318(483)	265(338)	177(245)	179(248)
90th	358(786)	395(699)	297(482)	181(251)	181(251)
Active	1	0	7	8	7
(Active and Overdue)	(1)	(0)	(1)	(1)	(1)
On Hold[h]	5	7	15	13	5
Total	**6**	**7**	**22**	**21**	**12**
Approved	48	31	26	6	4
Denied	0	0	0	0	0
Withdrawn	15	9	6	0	0
Other	2	2	0	0	0
Under Review	1	0	7	8	7
On Hold[h]	5	7	15	13	5
Total	**71**	**49**	**54**	**27**	**16**

*/ For each fiscal year, September 30, 2004 was used as the cutoff date. The FY04 cohort represents only receipts through March 31, 2004 (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 01 – FY 04

(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 01 - FY 04

	FY01	FY02	FY03	FY04 OIVD/ODE	FY04 ODE Only
Number Received	641	645	666	635	565
PMA Supplement Actions					
Panel Track Filing Decisions[a]					
Filed	11	24	5	6	6
Not Filed	4	1	1	1	1
Other	0	0	0	0	0
Filing Decision Subtotal	**15**	**25**	**6**	**7**	**7**
Scientific Review Decisions					
Major Deficiencies	9	12	6	4	3
Minor Deficiencies	0	0	0	0	0
Other[b]	78	93	91	87	78
Scientific Review Decisions Subtotal	**87**	**105**	**97**	**91**	**81**
Approval Decisions					
Panel Track Approvals[c]	11	16	11	5	4
Nonpanel Track Approvals	431	517	483	461	420
Approvable	100	102	96	68	65
Not Approvable	52	51	47	64	62
Approval Decision Subtotal	**594**	**686**	**637**	**598**	**551**
Total PMA Supplement Actions	**696**	**816**	**740**	**696**	**639**
Average Review Time (Days) for Approvals[d]					
FDA	71	85	72	68	67
Non-FDA	26	20	21	39	19
Total	**97**	**105**	**93**	**107**	**86**
Average Elapsed Time (Days) for Approvals[e]					
FDA	78	96	85	81	80
Non-FDA	32	28	26	46	26
Total	**110**	**124**	**111**	**127**	**106**
Number Under Review at End of Period[f]					
Active[g]	155	127	119	112	106
(Active and Overdue)	(9)	(2)	(4)	(4)	(4)
On Hold[h]	92	95	110	99	94
Total	**247**	**222**	**229**	**211**	**200**

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

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

(Continued on next page.)

Table 6. PMA Supplement Decision Cohort Performance
FY 01 - FY 04

(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 01 - FY 04

	FY01	FY02	FY03	FY04 OIVD/ODE	FY04 ODE Only
PMA Supplements Filed					
PMA Supplements	623	625	654	305	279
Expedited PMA Supplements	0	0	0	0	0
Total	**623**	**625**	**654**	**305**	**279**
PMA Supplement Final Actions[a]					
Approvals	472	500	481	206	191
Denials	0	0	0	0	0
Other[b]	139	108	157	84	74
Filing to First Action Excluding withdrawals, conversions, etc.[c,d]					
Number Received and Filed	623	625	654	305	279
Number of First Actions	603	604	627	290	265
Average FDA Days	71	71	64	55	55
Median FDA Days	36	36	32	30	30
Number (%) of First Actions within 180 Days	570(95)	583(97)	615(98)	287(99)	263(99)
Filing First Action Including withdrawals, conversions, etc.[e]					
Number Received and Filed	623	625	654	305	279
Number of First Actions	621	625	653	301	276
Average FDA Days	71	73	62	55	55
Median FDA Days	35	36	30	30	30
Number (%) of First Actions within 180 Days	587(95)	599(96)	641(98)	298(99)	274(99)
Filing to Final Action Excluding withdrawals, conversions, etc.[f]					
Number Received and Filed	623	625	654	305	279
Number of First Actions	581	576	603	272	251
Average FDA (Total) Review Days	79(100)	77(100)	65(81)	55(62)	55(62)
Median FDA (Total) Review Days	33(43)	35(46)	30(38)	30(30)	30(30)
Number (%) of Final Actions within 180 Days	522(90)	525(91)	570(95)	265(97)	245(98)
Number (%) of Final Actions within 180 Total Days	490(84)	500(87)	555(92)	260(96)	240(96)
Filing to Final Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	623	625	654	305	279
Number of First Actions	610	608	633	289	264
Average FDA (Total) Review Days	81(105)	80(107)	64(81)	53(61)	54(61)
Median FDA (Total) Review Days	34(44)	36(49)	30(39)	30(31)	30(31)
Number (%) of Final Actions within 180 Days	547(90)	550(90)	600(95)	282(98)	258(98)
Number (%) of Final Actions within 180 Total Days	509(83)	516(85)	581(92)	277(96)	253(96)
Average Number of FDA Cycles from Receipt to					
Final Action Including withdrawals, conversions, etc.[a]	1.1	1.1	1.0	1.0	1.0

Table 7. PMA Supplement Receipt Cohort Performance*
FY 01 - FY 04

(Continued from previous page.)

	FY01	FY02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Percentile FDA Days from Filing to First Action[d]					
25th	24	20	23	23	24
50th (Median)	36	36	32	30	30
75th	127	137	117	99	99
90th	180	179	178	175	174
Percentile FDA Days from Filing to First Action[e]					
25th	23	20	23	22	24
50th (Median)	35	36	30	30	30
75th	120	130	101	86	88
90th	178	177	168	152	151
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	24(27)	19(27)	23(28)	21(26)	22(27)
50th (Median)	33(43)	35(46)	30(38)	30(30)	30(30)
75th	124(151)	136(160)	97(113)	79(88)	83(88)
90th	181(212)	180(215)	174(178)	149(165)	148(161)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	23(27)	20(27)	23(28)	22(26)	24(27)
50th (Median)	34(44)	36(49)	30(39)	30(31)	30(31)
75th	126(160)	140(164)	92(113)	65(85)	75(86)
90th	181(233)	180(239)	170(178)	148(162)	148(161)
Number Pending as of 9/30/01					
Active	0	0	5	5	4
(Active and Overdue)	(0)	(0)	(2)	(2)	(2)
On Hold[h]	13	17	16	11	11
Total	**13**	**17**	**21**	**16**	**15**
Summary of PMA Supplement Receipt Cohort					
Approved	472	500	481	206	191
Denied	0	0	0	0	0
Withdrawn	28	26	30	18	14
Other	111	82	127	66	60
Under Review	0	0	5	5	4
On Hold[h]	13	17	16	11	11
Total	**624**	**625**	**659**	**306**	**280**

*/ For each fiscal year, September 30, 2004 was used as the cutoff date. The FY04 cohort represents only receipts through March 31, 2004 (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 01 - FY 04

(Continued from previous page.)

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

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

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

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

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

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

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

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

Table 8. PMA Panel Track Supplement Receipt Cohort Performance*
FY 01 – FY 04

	FY01	FY02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
PMA Panel Track Supplements Filed					
Panel Track PMA Supplements	13	17	6	0	0
Expedited Panel Track PMA Supplements	1	3	1	2	2
Total	**14**	**20**	**7**	**2**	**2**
Filing Decisions[a]					
Filed	14	20	7	2	2
Not Filed	2	1	1	0	0
Number of Filing/Not Filing Decisions with 45 Days	14	15	7	1	1
Average Days/Cycle	38	47	37	43	43
PMA Panel Track Supplement Final Actions[b]					
Approvals	12	18	4	1	1
Denials	0	0	0	0	0
Other[c]	3	1	2	1	1
Filing to First Action Excluding withdrawals, conversions, etc.[d]					
Number Received and Filed	14	20	7	2	2
Number of First Actions	14	20	7	2	2
Average FDA Days	136	144	118	148	148
Median FDA Days	135	158	109	148	148
Number (%) of First Actions within 180 Days	13(93)	18(90)	7(100)	2(100)	2(100)
Filing First Action Including withdrawals, conversions, etc.[e]					
Number Received and Filed	14	20	7	2	2
Number of First Actions	14	20	7	2	2
Average FDA Days	136	144	118	148	148
Median FDA Days	135	158	109	148	148
Number (%) of First Actions within 180 Days	13(93)	18(90)	7(100)	2(100)	2(100)
Filing to Final Action Excluding withdrawals, conversions, etc.[f]					
Number Received and Filed	14	20	7	2	2
Number of First Actions	11	18	4	1	1
Average FDA (Total) Review Days	241(319)	236(301)	238(273)	169(169)	169(169)
Median FDA (Total) Review Days	221(276)	200(230)	233(254)	169(169)	169(169)
Number (%) of Final Actions within 180 Days	5(45)	6(33)	1(25)	1(100)	1(100)
Number (%) of Final Actions within 180 Total Days	4(36)	3(17)	1(25)	1(100)	1(100)
Filing to Final Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	14	20	7	2	2
Number of First Actions	13	19	5	1	1
Average FDA (Total) Review Days	244(341)	231(320)	238(316)	169(169)	169(169)
Median FDA (Total) Review Days	221(276)	200(234)	234(273)	169(169)	169(169)
Number (%) of Final Actions within 180 Days	6(46)	7(37)	1(20)	1(100)	1(100)
Number (%) of Final Actions within 180 Total Days	4(31)	3(16)	1(20)	1(100)	1(100)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[b]	1.8	1.6	2.0	1.0	1.0

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Table 8. PMA Panel Track Supplement Receipt Cohort Performance* FY 01 – FY 04

(Continued from previous page.)

	FY01	FY02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Percentile FDA Days from Filing to First Action[d]					
25th	81	119	93	126	126
50th (Median)	135	158	109	148	148
75th	174	174	145	169	169
90th	180	191	179	169	169
Percentile FDA Days from Filing to First Action[e]					
25th	81	119	93	126	126
50th (Median)	135	158	109	148	148
75th	174	174	145	169	169
90th	180	191	179	169	169
Percentile FDA (Total) Days from Filing to Final Action[f]					
25th	174(174)	171(216)	206(207)	169(169)	169(169)
50th (Median)	221(276)	200(230)	233(254)	169(169)	169(169)
75th	288(539)	334(415)	270(339)	169(169)	169(169)
90th	313(555)	385(494)	305(404)	169(169)	169(169)
Percentile FDA (Total) Days from Filing to Final Action[g]					
25th	175(175)	170(216)	232(234)	169(169)	169(169)
50th (Median)	221(276)	200(234)	234(273)	169(169)	169(169)
75th	288(539)	334(438)	244(404)	169(169)	169(169)
90th	343(664)	385(546)	305(489)	169(169)	169(169)
Number Pending as of 9/30/02					
Active	0	0	0	2	2
(Active and Overdue)	(0)	(0)	(0)	(0)	(0)
On Hold[h]	2	1	1	0	0
Total	**2**	**1**	**1**	**2**	**2**
Summary of PMA Supplement Receipt Cohort					
Approved	12	18	4	1	1
Denied	0	0	0	0	0
Withdrawn	3	1	2	1	1
Other	0	0	0	0	0
Under Review	0	0	0	2	2
On Hold[h]	2	1	1	0	0
Total	**17**	**20**	**7**	**4**	**4**

*/ For each fiscal year, September 30, 2004 was used as the cutoff date. The FY04 cohort represents only receipts through March 31, 2004 (first 6 months of the fiscal year). The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus the average elapsed time is the average time taken to obtain approval of a PMA from its filing date until it receives final approval.

(Continued on next page.)

Table 8. PMA Panel Track Supplement Receipt Cohort Performance*
FY 01 – FY 04

(Continued from previous page.)

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

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

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

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

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

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

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

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

Table 9. HDE Submissions Received
FY 01 – FY 04

TYPE OF SUBMISSION	NUMBER RECEIVED				
	FY01	FY02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Humanitarian Device Exemptions (HDEs)					
Original Applications	5	5	10	9	9
Amendments	62	54	41	53	53
Supplements	16	16	29	29	28
Amendments to Supplements	8	20	25	18	17
Reports for Original Applications	24	29	37	16	16
Reports for Supplements	0	0	0	0	0
Total	**115**	**124**	**142**	**125**	**123**

Table 10. Original HDE Decision Cohort Performance
FY 01 – FY 04

	FY 01	FY 02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Number Received	5	5	10	9	8
HDE Action					
Filing Decisions					
Filed	6	6	6	7	6
Not Filed	1	1	5	2	2
Others[a]	0	0	2	0	0
Filing Decisions Subtotal	**7**	**7**	**13**	**9**	**8**
Scientific Review Decisions					
Major Deficiencies	7	6	4	5	3
Minor Deficiencies	6	2	3	3	3
Other[b]	2	0	2	13	12
Scientific Review Decisions Subtotals	**15**	**8**	**9**	**21**	**18**
Approval Decisions					
Approvals	4	6	2	6	5
Approvable	0	0	0	3	2
Not Approvable	0	0	0	0	0
Denials	0	0	0	0	0
Approved Decision Subtotal	**4**	**6**	**2**	**9**	**7**
Other Final Decisions[c]	4	2	2	5	5
Total HDE Actions	**30**	**23**	**26**	**44**	**38**
Filing to First Action[d]					
Number of First Actions	6	6	3	7	7
Average Number of FDA Days	42	53	48	52	52
Number of First Actions Within 75 Days	6	5	2	7	7
Average Elapsed Time (Days) for Approvals[e]					
FDA	143	175	152	182	195
Non-FDA	100	127	96	94	92
Total	**243**	**302**	**248**	**276**	**287**
Average Number of FDA Cycles from Receipt to Final Action[f]	1.9	2.1	2.0	2.0	2.0
Number under Review at End of Period[g]					
Active[h]	1	1	4	4	4
Active and Overdue	0	0	0	1	1
On Hold[i]	6	3	6	4	3
Total	**7**	**4**	**10**	**9**	**8**

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

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

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

(Continued on next page.)

Table 10. Original HDE Decision Cohort Performance

FY 01 – FY 04

(Continued from previous page.)

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

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

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

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

h/ The application is under review by FDA.

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

Table 11. HDE Supplement Decision Cohort Performance FY 01 – FY 04

	FY01	FY02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Number Received	16	16	29	29	28
HDE Supplement Actions					
Scientific Review Decisions					
Major Deficiencies	0	0	0	3	3
Minor Deficiencies	0	0	1	2	2
Other[a]	1	1	3	3	3
Scientific Review Decisions Subtotal	**1**	**1**	**4**	**8**	**8**
Approval Decisions					
Approvals	11	13	24	23	22
Approvable	0	6	5	6	6
Not Approvable	1	6	6	4	3
Denials	0	0	0	0	0
Approval Decision Subtotal	**12**	**25**	**35**	**33**	**31**
Other Final Decisions[b]	1	1	2	7	7
Total HDE Actions	**13**	**27**	**37**	**40**	**38**
Filing to First Action[c]					
Number of First Actions	12	17	29	39	37
Average Number of FDA Days	52	53	37	39	36
Number of First Actions within 75 Days	8	16	26	18	18
Average Elapsed Time (Days) for Approvals[d]					
FDA	46	60	43	66	61
Non-FDA	0	14	52	29	29
Total	**46**	**74**	**95**	**95**	**90**
Average Number of FDA Cycles from Receipt to Final Action[e]	1.0	1.3	1.0	1.2	1.2
Number Under Review at End of Period[f]					
Active[g]	4	4	5	7	7
(Active and Overdue)	0	0	0	0	0
On Hold[h]	1	4	6	4	4
Total	**5**	**8**	**11**	**11**	**11**

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

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

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Table 11. HDE Supplement Decision Cohort Performance FY 01 – FY 04

(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 01 - FY 04

	FY01	FY02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Number Received	284	312	242	226	222
Number of Decisions					
Approved	208	209	146	149	146
Not Approved	53	75	78	53	52
Other[a]	23	23	22	19	19
Total	**284**	**307**	**246**	**221**	**217**
Percent (%) of Approvals Made during First Review Cycle[b]	80	74	65	74	74
Average FDA Review Time (days)	28	28	27	28	28
Percent (%) of Decisions Made within 30 Days	100	99	100	100	100
Number under Review at End of Period[c]	18	22	18	23	23
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 01 - FY 04

	FY01	FY02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Amendments Received[a]	206	252	216	167	167
Decisions on Amendments					
Approved	73	86	73	61	61
Not Approved	39	55	40	27	27
Other[b]	95	110	104	74	74
Total	**207**	**251**	**217**	**162**	**162**
Average FDA Review Time (days)	18	18	19	18	18
Percent (%) of Decisions Made within 30 Days	99	100	100	100	100
Average Approval Time (days) For IDEs with Amendments					
FDA Time	59	68	68	61	61
Non-FDA Time	82	67	112	100	100
Total Time[c]	**141**	**135**	**180**	**161**	**161**
Number of Amendments per Approved IDE	1.7	2.2	2.1	1.8	1.8
Amendments under Review at End of Period[d]	8	7	6	11	11
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 01 - FY 04

	FY02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Number Received	4,724	4,415	4,312	4,298
Number of Decisions	4,711	4,424	4,348	4,336
Average FDA Review Time (days)	20	19	19	19
Percent (%) OF Decisions Made within 30 Days	100	100	100	100
Number under Review at End of Period[a]	260	249	212	210
Number Overdue at End of Period	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 01 – FY 04

	FY01	FY02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Number Originals Received	4,248	4,320	4,247	3,635	3,110
Number of Decisions					
Substantially Equivalent	3,428	3,667	3,522	3,460	2,988
Not Substantially Equivalent	46	69	88	114	88
Other[a]	676	640	522	343	300
Total	**4,150**	**4,376**	**4,132**	**3,917**	**3,376**
Percent (%) Not Substantially Equivalent[b]	1.3	1.8	2.4	3.2	2.9
Average Review Time (Days)					
FDA Time[c]	75	79	76	74	75
Total Time[d]	96	100	96	100	103
Median Review Time (Days)					
FDA Time[c]	68	70	65	61	62
Total Time[d]	72	74	72	70	72
Percent(%) of Decisions made within 90 Days, based on					
FDA Time[e]	100	100	99	100	100
Total Time[d]	69	69	69	65	64
Number under Review at End of Period[f]					
Active[g]	934	935	1,015	652	561
(Active and Overdue)	0	0	0	0	0
On Hold[h]	382	337	376	441	378
Total	**1,316**	**1,272**	**1,391**	**1,093**	**939**

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, and other miscellaneous act a duplicate, not a device, a general purpose article, exempted by regulation,

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 01 - FY 04

	FY01	FY02	FY03	FY04 OIVD/ ODE	FY04 ODE Only
Number of 510(k)s Received[a]					
Traditional	3,370	3,352	3,157	1,991	1,667
Special	710	786	862	596	548
Abbreviated	174	184	206	89	75
Total Receipts	**4,254**	**4,322**	**4,225**	**2,676**	**2,290**
Actions on 510(k)s					
Substantially Equivalent	3,574	3,566	3,597	2,118	1,817
Not Substantially Equivalent (%)[b]	61(1.7)	71(2)	109(2.9)	53(2.4)	41(2.2)
Other[c]	617	621	453	121	96
Total Actions	**4,252**	**4,258**	**4,159**	**2,292**	**1,954**
Average Cumulative Days for 510(k) Decisions Excludes Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	79	75	74	57	58
Total Time from Receipt to Final Decision[e]	99	91	95	70	71
All Decisions Including Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	78	74	73	56	57
Total Time from Receipt to Final Decision[e]	107	101	104	71	71
Number of Decisions (%) with 90 Days, Based on:					
FDA Days from Receipt to First Action	4,245(100)	4,311(100)	4,212(100)	2,670(100)	2,285(100)
FDA Cumulative Days from Receipt to Final Decisions	3,264(77)	3,377(78)	3,222(76)	2, 015(75)	1,712(75)
Total Cumulative Days from Receipt to Final Decisions[e]	2,889(68)	3,018(70)	2,848(67)	1,779(66)	1,517(66)
Average Number of FDA Cycles from Receipt to Final Action	1.4	1.4	1.5	1.4	1.4
Percentile FDA (Total) Days from Receipt to Final Action					
25th	31(35)	30(34)	29(30)	28(29)	28(29)
50th (Median)	70(77)	69(76)	64(74)	62(72)	62(73)
75th	90(145)	90(130)	90(146)	90(136)	91(139)
90th	162(237)	162(252)	168(270)	N/A(N/A)	N/A(N/A)
Number under Review as of 9/30/01					
Active	2	17	19	126	117
Active and Overdue	0	0	0	0	0
On Hold	0	47	47	257	218
Total	**2**	**64**	**66**	**383**	**335**
Summary of 510(k) Receipt Cohort					
Substantially Equivalent	3,574	3,566	3,597	2,118	1,817
Not Substantially Equivalent	61	71	109	53	41
Other	617	621	453	121	96
Under Review	2	17	19	126	117
On Hold	0	47	47	257	218
Total	**4,254**	**4,322**	**4,225**	**2,676**	**2,290**

(Continued on next page.)

Table 16. 510(k) Receipt Cohort Performance*
FY 01 – FY 04

(Continued from previous page.)

*/ For each fiscal year, September 30, 2004 was used as the cutoff date. The FY03 cohort represents only receipts through June 30, 2004 (first nine months of the fiscal year).

a/ Includes Third Party 510(k)s: FY01 =107; FY02 = 127; FY03 = 190; FY04=182 (9 months)

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

c/ Includes final administrative actions that did not result in a substantially equivalent/not substantially equivalent decision because the 510(k) or device/product was: withdrawn by the applicant, deleted due to lack of response, a duplicate, not a device, a 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

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Ciarkowski, Art
Chakrabarti, Kish
Cotterell, Alison
Gatling, Robert
Hawthorn, Anne
Jensen, D. Nick
Kammula, Raju
Less, Joanne
Lewis, Brian
Mann, Eric
Melkerson, Mark
Neuland, Carolyn
Nguyen, Thinh
Pena, Carlos
Phillips, Philip
Pluhowski, Nancy
Provost, Miriam
Rosecrans, Heather
Sacks, William
Wolanski, Nicole

ODE Standards Liaison Representatives

Abel, Dorothy
Adjodha, Michael
Allen, Peter
Anderson, Jodi
Baker, Karen
Basu, Sankar
Beers, Everette
Berman, Michael
Berman, Sheryl
Bezabeh, Shewit
Blackwell, Angela
Brown, Daniel
Burdick, William
Byrd, Laura
Calogero, Don
Carey, Carole
Chen, Tzeng
Cheng, Jim
Ciarkowski, Art
Cornelius, Mary Jo
Cunningham, Terrell
Cygnarowicz, Teresa
Dawisha, Sahar
Daws-Kopp, Kathryn
DeLuca, Robert
Demian, Hany
Doyle, Bob
Drum, Bruce
Eydelman, Malvina
Felton, Richard

APPENDIX B

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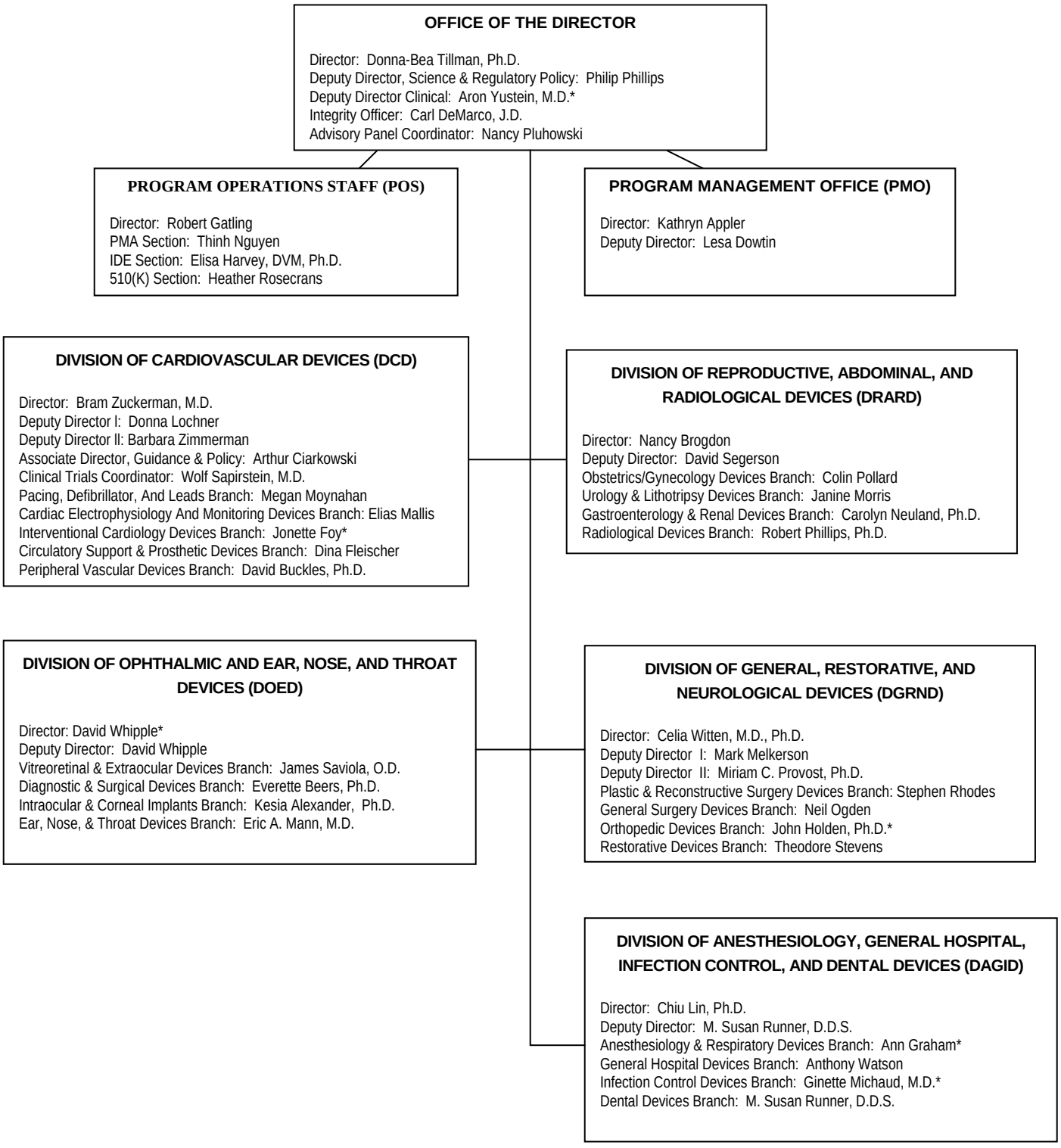
Fox, Pat
Foy, Jonette
Gantt, Doyle
Gonzalez, Gema
Goode, John
Gouge, Susan
Guay, Justin
Hinckley, Steve
Ho, Charles
Holden, John
Holt, Vivianne
Husband, Michael
Jensen, Nick
Kaiser, Aric
Kammula, Raju
Kane, James
Kang, Simkeon
Krause, David
Kuchinski, Michael
Lappalainen, Sharon
Lee, James
Lepri, Bernard
Letzing, Bill
Lin, Chiu
Malshat, Vasant
Marshall, Felicidad
Mattamal, George
Mayhall, Elaine
McCarthy, Denis
McCool, Barbara
Melkerson, Mark
Mishra, Nirmal
Mulry, Kevin
Naveau, Irene
Nell, Diane
Nimmagadda, Venkat
Nutter, Cathy
Ogden, Neil
O'Lone, Martha
Phillips, Robert
Pinto, Hina
Pollard, Collin
Rhodes, Stephen
Riley, Erin
Rosenthal, Ralph
Ryan, Michael
Saviola, James
Schmidt, Jennifer
Schroeder, Marie
Shein, Mitchell
Shi, Dexiu
Shih, Ming-Chuen
Smith, Myra
Stiegman, Glenn
Tillman, Donna-Bea
Toy, Jeffrey
Turtil, Steve
Warburton, Karen
Weitershausen, Joanna
Wentz, Catherine
Whipple, David
Witten, Celia
Wood, Geretta
Zaremba, Loren

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
Instructions for Submitting Electronic Submissions	http://www.fda.gov/cdrh/elecsub.html
LASIK Eye Surgery: Learning About LASIK	http://www.fda.gov/cdrh/lasik/
Least Burdensome Provisions - Activities Related to Implementation	http://www.fda.gov/cdrh/modact/leastburdensome.html
MDUFMA Home Page	www.fda.gov/cdrh/mdufma
OIVD Home Page	http://www.fda.gov/cdrh/oivd
Panel Meeting Schedules and Summaries	http://www.fda.gov/cdrh/panel/index.html
Previously Approved/Cleared Device Databases	http://www.fda.gov/cdrh/consumer/mda/index.html#databases
Recent Device Approvals	http://www.fda.gov/cdrh/consumer/mda/index.html
Recruitment Brochure for Members and Consultants to the Medical Devices Advisory Committee	http://www.fda.gov/cdrh/ode/advbrochure01.html
Standards of Ethical Conduct	http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/reference/rfsoc_99.pdf
Third Party Review	http://www.fda.gov/cdrh/thirdparty

Appendix D – ODE Organization Chart

As of 01/26/04



*Acting

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Doyle, Robert
Gornick, MaryAnn
Hobbs, Cathy
Phillips, Philip
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Williams, Nailah
Yustein, Ron

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Jaeger, Jeff
Koviack, Bob♦
Phillips, Shirley
Robins, Lisa♦
Schielke, Mary
Soto, Isella♦
Wedlock, Chuck

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Berk, Gene
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Fisher, Lisa
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Gatling, Robert
Harvey, Elisa
Hawthorn, Anne
Less, Joanne
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Melvin, Marsha
Nguyen, Thinh
Rechen, Eric
Romanell, Lawrence
Rosecrans, Heather
Sawyer-Major, Wanda
Simenauer, Paula
Shulman, Marjorie
Stuart, Brandi
Wolanski, Nicole

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Anderson, Evan
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Bowley, Susan
Brown, Michele
Buckles, David
Buckley, Donna
Carey, Carole**
Cavanaugh, Kenneth
Chandeysson, Paul
Chen, Eric
Cheng, Jim
Ciarkowski, Art
Correa, Gina++
Demian, Cindy
Donelson, Jan
Enyinna, Kachi
Ewing, Lesley**
Farb, Andrew
Faris, Owen
Fleischer, Dina
Foy, Joni
Foy, Keith
Gantt, Doyle
Goode, Jennifer
Heaton, Henry (Tom)**
Higginson, Kathy++
Hill, Genevieve++

Hillebrenner, Matthew
Ho, Charles
Holden, John
Holt, Vivianne
Hottenstein, Omar
Huynh, Ann
Hwang, Shang
Hyde, John
Jensen, Nick
Jones, Edwena
Kaiser, Suzanne
Kennell, Lisa
Krueger, Matt
Kurtzman, Steve
Lacy, Frank
Lappalainen, Sharon[#]
Lee, James
Lemperle, Bette
Letzing, Bill
Lewis, Brian
Lochner, Donna
Mallis, Elias
Mattera, Michelle
Mezu-Nwaba, Nina
Moynahan, Megan
Muni, Neal
Nell, Diane[#]
Ogden, Neil
Peters, Kimberly
Pinto, Hina
Ramdat, Deb
Reilly, Sabina
Richards, Robert[++]
Ryan, Tara
Samadnejad, Sami
Sapirstein, Wolf
Shein, Mitchell
Smallwood, Senora
Smith, Angela
Stiegman, Glenn
Stuhlmuller, John
Swain, Julie**
Swink, James
Terry, Doris
Tovar-Calderon, Oscar[+]
Tritschler, Elizabeth
Ulmer, Kwame
Usher, Wil
Vaughan, Carolyn
Wentz, Catherine
Wood, Geretta
Yuan, Jay
Zimmerman, Barbara
Zuckerman, Bram

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Bezabeh, Shewit
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Blount, Sharon
Bolden, Brenda
Browne, Myra
Burdick, William
Chisley, India
Colburn, Scott
Cotterell, Alison
Cricenti, Pat
Cunningham, Terrell
Floyd, Chirelle
Fox, Pat
Gantt, Gail
Graham, Ann
Guay, Justin
Harkavy, Lorraine
Hibbard, Viola
Husband, Michael
Jordan, Erika
Leveille, Lisa
Lin, Chiu
Lippman, Jason
Maloney, Bill
Marshall, Felicidad
Mayhall, Elaine
Mulry, Kevin
Nakayama, Von

Naveau, Irene
O'Connell, Linh
O'Lone, Martha
Patel, Neel
Pinto, Hina
Ralston, Luke
Reid, Joy
Riley, Erin
Rios, Michelle
Rizk, Sarah**
Robinson, Mary Jo
Roy, Joydeb
Runner, Susan
Ryan, Michael
Sauberman, Harry
Soprey, Pandu
Teresinski, Doris
Tritschler, Elizabeth
Turtil, Steve
Weininger, Sandy#
Weitershausen, Joanna

Division of General, Restorative, and Neurological Devices

Allen, Peter
Allen, Samie
Anderson, Jodi
Arepalli, Sambasiva
Ashar, Binita
Basu, Sankar
Berkowitz, David
Bernato, Dolores
Berne, Bernard
Bowsher, Kristen
Brown, Sheila
Buch, Barbara
Corn, David
Costello, Ann
Courtney, Michael
Cox, Ann#
Dawisha, Sahar
De Del Castillo, Sergio
DeLuca, Robert
Demian, Hany
Durfor, Charles
Eggleton, Justin
Einberg, Elmar
Eudy, Michael
Felten, Richard
Ferriter, Ann
Fogarty, Pauline
Frank, Elizabeth
Gantenberg, Julie**
Goode, John
Hack, Christopher
Hackey, Elise
Hammond, Della
Hanafi, Nada
Herzog, Calley
Hill, Ayanna
Hill, Genevieve++
Hinckley, Steve
Horbowyj, Roxi
Hudson, Peter
Janda, Michel
Kaiser, Aric
Kattekola, Brunda**
Krause, David
Lee, Kyung
Lerner, Herbert
Marjenin, Timothy++
Mattamal, George
Melkerson, Mark
Mills, Kristin
Mishra, Nirmal
Pak, Yung
Peck, Jonathan
Pena, Carlos
Phillips, Mary Ellen
Popovic, Neven
Provost, Miriam
Rhodes, Hollace
Rhodes, Stephen
Rossi, Jeffrey
Schlosser, Michael
Schroeder, Marie
Scudiero, Janet
Sloan, Nadine
Stevens, Theodore
Stiegman, Glenn

Sturniolo, Michael
Sun, Yang**
Sung, Pei
Tillman, Ahlia**
Vegas-Sala, Dora
Walker, Jeffrey
Warfield, Diane
Watson, Anthony
Weiblinger, Richard
Witten, Celia
Wolf, Beverly
Wood, Gregory
Yahiro, Martin
Yen, Dwight
Zimliki, Charles#

Division of Ophthalmic and Ear, Nose, and Throat Devices

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

Division of Reproductive, Abdominal, and Radiological Devices

Bailey, Michael
Baxley, John
Bradley Allen, Cheryl
Breeher, Laura**
Brogdon, Nancy
Byrne, Michelle
Carr, Linda
Chakrabarti, Kish
Chan, Dulciana#
Chen, John
Cooper, Jeffrey
Cornelius, Mary Jo
Corrado, Julia
Czerska, Ewa
Dart, Linda
Daws-Kopp, Kathryn
Del Mundo, Noel
Eba, Felisa

Gonzalez, Gema
Grillo, Greg
Hayes, Wendelin
Herrera, Hector
Howell, Kimberly
Isayeva, Irada[#]
Jevtich, Milorad
Kammula, Raju
Kang, Simkeon
Kuchinski, Michael
Lauritsen, Kristina
Mackey, Cheryl
McCool, Barbara
Miller, Patricia
Mitchell, Diane
Morris, Janine
Neuland, Carolyn
Nimmagadda, Venkat Rao
Nipper, Joshua
Nutter, Cathy
O'Brien, Mary Beth
Oliver, Karen
Olvey, Kathleen
Paquerault, Sophie[#]
Perez, Rodrigo
Phillips, Robert
Pollard, Colin
Price, Veronica
Rubendall, Rita
Ruiz, Claudia**
Sacks, William
Sauls, Mattie
Segerson, Dave
Seiler, Jim
Shoback, Barbara[##]
Shuping, Ralph
Stephenson, Rebecca
Straughn, Kellie
Stratton, Michael "Slade"[++]
Tai, Mary Ann[++]
Virmani, Mridulika
Vorvolakos, Katherine**
Wersto, Nancy
Whang, Joyce
Williams, Richard
Zaremba, Loren

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** ORISE Contractor
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[##] Joint Appointment w/OCER
[+] MDUFMA Joint Hire w/OSB
[++] Co-Op Employee
♦ Shared Services