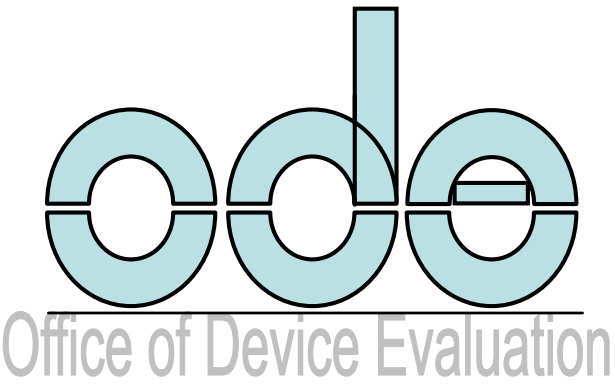
OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 2005



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

Protecting and Promoting Public Health

Acknowledgements

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

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

Miriam Provost, Project Director
Cathy Hobbs, Editor
MaryAnn Gornick, Production Specialist

Table of Contents

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

PREFACE

Dear Reader:

Henry David Thoreau instructed us that 'Our life is frittered away by detail... Simplify, simplify.' We have taken his words to heart in developing this year's ODE Annual Report. There are three reasons for this change: 1) MDUFMA has caused us to reassess how we think about our premarket review performance, and we wanted to present a more balanced view of our accomplishments; 2) It was time to recognize that the bold experiment that created OIVD had become the new reality, and thus it was time to start presenting ODE-only data. The historical data that we had was combined ODE/OIVD; and 3) We have discovered limitations in the computerized reporting system that we had historically used to generate these tables. In addition, we have provided a link (www.fda.gov/cdrh/mdufma) to the performance data we have tracked, reported, and updated under MDUFMA. We think those measures are significant because we negotiated those goals with industry as the way to get safe and effective products to market most effectively; therefore, these are the goals to which we are managing. That being said, if there are performance statistics that we have not reported that are important to you, we encourage you to let us know by sending your comments to odereports@fda.hhs.gov. We will consider your comments in developing next year's ODE Annual Report.

In the meantime, I am excited to share with you a summary of the highlights of our accomplishments for FY 05. Yes, we are meeting, and in some cases exceeding, nearly all of the MDUFMA performance goals. But after reading this report, I hope that you will see that the impact of what we (and the Industry we regulate) have accomplished goes beyond improving the timeliness of the review process. Each and every day ODE staff are fulfilling FDA's public health mandate in a thousand different ways. Whether it be emergency preparedness for pandemic flu, developing better clinical trials for the next generation drug-eluting stent, or following up on pediatric patients with cochlear implants, ODE staff are playing a critical role. This annual report provides the highlights of what they have achieved in FY 05. I am proud to be part of their team, and I look forward to what we will achieve together in the following years.

Donna-Bea Tillman,
Ph.D. Director
Office of Device Evaluation

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.

New technology for destruction of uterine fibroids

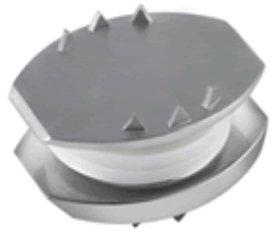
The ExAblate 2000 System by InSightec, Ltd. uses magnetic resonance image guided focused ultrasound to target and destroy uterine fibroids. The device is intended to treat women who have completed child bearing or do not intend to become pregnant.

The ExAblate provides a uterine-sparing alternative for women experiencing problems from uterine fibroids using a non-invasive surgical treatment. The ExAblate combines two systems: 1) a magnetic resonance imaging (MRI) device to visualize patient anatomy, map the volume of fibroid tissue to be treated, and monitor the temperature of the uterine tissue after heating, and 2) a focused ultrasound beam that heats and destroys the fibroid tissue using high frequency, high-energy sound waves. This is the first time these two systems have been combined and the first time MRI has been used to monitor tissue temperature. The treatment requires repeated targeting and heating of fibroid tissue while the patient lies inside the MRI machine. The procedure can last as long as three hours.

DuraSeal Dural Sealant System

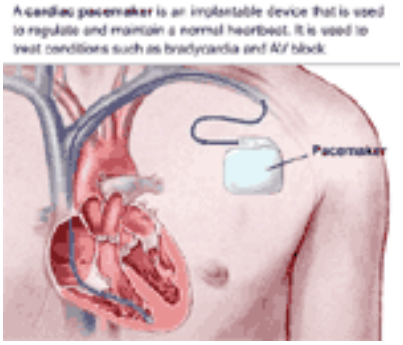
The DuraSeal Dural Sealant System by Confluent Surgical, Inc. is the first material approved for sealing leaks in the dura mater during neurosurgical procedures. The sealant is composed of two solutions, a polyethylene glycol (PEG) ester solution and a trilysine amine solution referred to as the blue and clear precursor solutions. When mixed together, the precursors provide rapid in situ polymerization to form a hydrogel that seals the dura mater. DuraSeal Dural Sealant is intended to aid in preventing cerebrospinal fluid leakage through suture-approximated wound edges. The sealant is sprayed or layered onto sutured dural wound edges and allowed to polymerize in place. The blue colorant allows users to easily visualize application of the sealant. The sealant is absorbable and will biodegrade within 4-8 weeks after application.

CHARITÉ™ Artificial Disc



The CHARITÉ™ Artificial Disc by DePuy Spine, Inc. is the first non-fusion device intended to replace a diseased or damaged intervertebral disc (spinal arthroplasty) to treat pain associated with degenerative disc disease (DDD). DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. The CHARITÉ™ consists of two metal (cobalt-chrome alloy) endplates that are anchored to the top and bottom surfaces of the spinal bones (vertebrae) and a plastic (ultra-high molecular weight polyethylene or UHMWPE) core that fits between the two endplates. The plastic core and endplates help restore the natural distance between the two vertebrae (disc height). The endplates can slide over the domed parts of the core, which can allow movement at the level where it is implanted. The CHARITÉ™ Artificial Disc is indicated for spinal arthroplasty in patients who are skeletally mature, have DDD at one level in the lumbar spine (from L4-S1), have no more than 3mm of spondylolisthesis at the involved level, and have had no relief from pain after at least six months of non-surgical treatment.

New lead wire for pacemakers

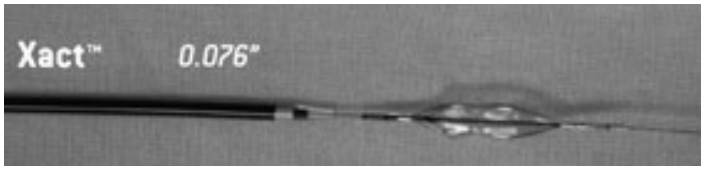


The Medtronic® SelectSecure™ Lead Model 3830, manufactured by Medtronic, Inc., is a surgically implanted wire that connects the heart to an implanted pacemaker. A pacemaker is a small, battery-operated electronic device which is inserted under the skin to help the heart beat regularly and at an appropriate rate. The SelectSecure™ Lead Model 3830, in conjunction with an implanted pacemaker, treats irregular or slow heart rhythm (bradycardia). If bradycardia is not treated, it can lead to fatigue, shortness of breath, dizziness, or fainting. The SelectSecure™ Lead Model 3830 allows a pacemaker to monitor and pace the heart and slowly releases a steroid (Beclomethasone Dipropionate) into the body to improve healing of the lead attachment site after implantation. The SelectSecure™ Lead Model 3830 is used when implantable atrial or ventricular, single-chamber or dual-chamber pacing systems are indicated.

New endovascular graft for treatment of aneurysms

The GORE TAG Thoracic Endoprosthesis (a prosthetic endovascular graft) by W.L. Gore & Associates is used to repair aneurysms of the aorta in the chest (thoracic aorta). An aneurysm is a diseased, weakened and bulging section of an artery wall. The GORE TAG Thoracic Endoprosthesis is an endovascular graft made of ePTFE (expanded polytetrafluoroethylene), with a metallic support structure known as a stent. The endovascular graft is placed inside the weakened artery to prevent further growth and rupture of the aneurysm. The GORE TAG Thoracic Endoprosthesis is the first endovascular grafting system approved to treat aneurysms of the thoracic aorta. The GORE TAG Thoracic Endoprosthesis is used instead of more invasive open surgery in patients who have a descending thoracic aortic aneurysm.

Stent for prevention of future strokes



The Xact® Carotid Stent System by Abbott Vascular Devices is used in high risk carotid disease patients with either symptomatic carotid vascular disease and a ≥50% carotid blockage or in patients with a very tight blockage (≥80%) in their carotid artery as an alternative to the surgical procedure known as carotid endarterectomy. The Xact® Carotid Stent System has two components: the stent and delivery catheter system (Xact® Carotid Stent System) and an embolic protection system (Emboshield Embolic Protection System). The Xact® Carotid Stent System is intended to open blockages in the carotid blood vessel in order to prevent future strokes. The embolic protection device is intended to capture debris that may be dislodged during placement of the stent.

New technology for maintaining patient data

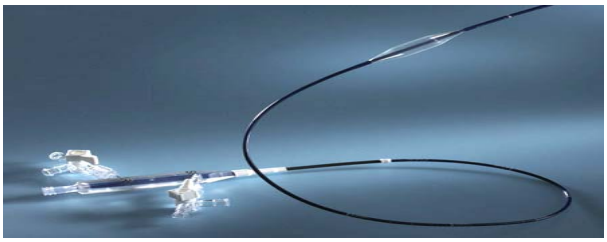
FDA approved, through the *de novo* process, the VeriChip™ Health Information Microtransponder System, consisting of an implantable chip, an introducer, and a reader. After the chip is implanted subcutaneously, a caregiver is able to retrieve a unique patient identifier and patient medical information from a prescription website when the patient is otherwise unable to provide this information. The medical information on the website is supplied by the patient and can only be accessed with appropriate authorization.

New prosthetic jaw joint

The Total Temporomandibular Joint Replacement System by Walter Lorenz Surgical, Inc. is a prosthetic jaw joint. The device is used for patients who need a total jaw replacement due to one or more of the following conditions: severe arthritic conditions, fused joints, previous multiple surgeries, severe fractures, tumors and severely degenerated joints. The device is a ball and socket joint with one side mounted to the jaw and the other side mounted to the head in front of the ear. A surgeon implants the joint after removing any old devices, unsuccessful grafts, and badly damaged bone. It may reduce jaw pain, reduce interference with eating and increase the ability to open the mouth.

Catheter to treat cerebral ischemia

The NeuroFlo™ Catheter by CoAxia, Inc. is used to treat cerebral ischemia, a condition that occurs when the brain does not receive enough blood flow to maintain normal neurologic function such as speech, movement, and understanding. The NeuroFlo™ Catheter is a long, flexible tube with two small balloons on one end that is used to partially block blood flow in large blood vessels. It is used for the treatment of cerebral ischemia resulting from symptomatic vasospasm in patients who have not responded to other forms of treatment. Symptomatic vasospasm is the squeezing down of a blood vessel in the brain that results in symptoms similar to stroke such as difficulty in speaking, movement, or understanding.



Monitoring leaks of vascular graft

FDA approved, through the *de novo* process, the CardioMEMS, a device intended for measuring intrasac pressure during endovascular abdominal aortic aneurysm (AAA) repair. The device is intended to be used as an adjunctive tool in the detection of intraoperative endoleaks. It is designed to be implanted in the abdominal aortic aneurysm (AAA) sac during the deployment of a stent-graft. It senses the pressure in the AAA sac so that information regarding possible endoleaks or AAA rupture can be collected.

Oral rinse for gingivitis

FDA approved, through the *de novo* process, a prescription oral rinse used to reduce the adhesion of dental plaque. Decapinol was cleared by CDRH as a medical device for the treatment of gingivitis because of its mechanism of action. Decapinol works by preventing attachments of bacteria to tooth surfaces rather than being bactericidal. Gingivitis, the earliest stage of gum disease, is an inflammation of the gums caused by a build up of bacteria that grow in the coating (plaque) that forms on teeth between brushings. The rinse forms a barrier that reduces bacterial attachment to tooth surfaces. The interference with bacterial attachment reduces the formation of plaque associated with gingivitis. The rinse is used in addition to normal oral hygiene such as brushing and flossing. It is intended to be used twice daily for one minute after brushing and flossing.

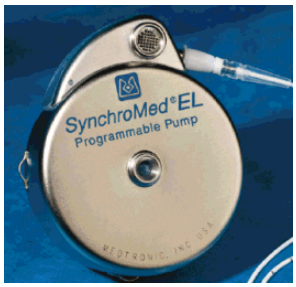
Surgical Laser for use in Assisted Reproductive procedures

FDA approved, through the *de novo* process, the Hamilton Thorne Zona Infrared Laser Optical System (ZILOS-th®). The device is used to drill a small tangential hole in the zona pellucida of embryos to facilitate embryo hatching prior to implantation. This device has been shown to increase implantation rates in older women (>37 years), and patients utilizing frozen embryos.

Laser Scanning Technology for Confocal Microscopy of the Cornea

The Heidelberg Engineering HRT II laser scanning technology combined with the Rostock Cornea Module (RCM) is the first FDA-cleared ophthalmic confocal laser scanning microscope for directly imaging a patient's cornea and anterior segment. The confocal laser scanning microscope is a valuable tool for obtaining high resolution images and 3-D reconstructions of thick specimens at various depths. Images are taken point-by-point and reconstructed with a computer, rather than projected through an eyepiece. This confocal microscope allows for imaging at different depths inside of the cornea, as well as the front of the eye, with high resolution.

Patient -administered analgesia control



The Patient Therapy Manager (PTM) accessory to the SynchroMed Implantable Infusion System allows a patient to self-administer a bolus of pain medication from the SynchroMed Implantable Infusion System based upon the parameters programmed by a physician. This is the first device for patient administered analgesia control for an implantable infusion pump.

Application Activity

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 2005, ODE approved 29 PMAs and 2 HDEs. These are listed below. We recommend turning to the PMA approval website, which is available at http://www.fda.gov/cdrh/consumer/mda, for easy-to-understand one pagers for each PMA approved. 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.

Original PMA/HDE Approvals for Fiscal Year 2005

		COMPANY	DEVICE
15-Oct-04	P030011	SynCardia Systems, Inc.	Syncardia temporary CardioWest Total Artificial Heart (TAH-t)
22-Oct-04	P040003	InSightec, Ltd.	InSightec ExAblate® 2000
26-Oct-04	P040006	DePuy Spine, Inc.	CHARITE™ Artificial Disc
29-Oct-04	P040002	Endologix, Inc.	Endologix PowerLink® System – Bifurcated Infrarenal Stent Grafts, Limb Extension, and Proximal Cuff
03-Nov-04	P040022	*angio*LINK Corporation	EVS™ Vascular Closure System
05-Nov-04	P030031	Biosense Webster, Inc.	Biosense Webster NaviStar™/Celsius™ ThermoCool® Diagnostic/Ablation Deflectable Tip Catheters
23-Nov-04	P030007	Eastman Kodak Company	Kodak Mammography CAD Engine

		COMPANY	DEVICE
03-Dec-04	P010029	Savient Pharmaceuticals, Inc.	Nuflexxa™ (1% Sodium Hyaluronate)
06-Dec-04	P040027	W.L. Gore & Associates	GORE VIATORR® TIPS
16-Dec-04	P030030	Genyx Medical, Inc.	URYX® Urethral Bulking Agent
17-Dec-04	P030022	Smith and Nephew, Inc.	Reflection® Ceramic Acetabular System
23-Dec-04	P030034	Orthofix, Inc.	Cervical-Stem® Model 505L Cervical Fusion System
14-Jan-05	P040014	Irvine Biomedical	IBI Therapy™ Cardiac Ablation System
21-Mar-05	P040020	Alcon Research Ltd.	The ACRYSOF® ReSTOR® Apodized Diffractive Optic Posterior Chamber Intraocular
23-Mar-05	P040043	W.L. Gore and Associates	GORE TAG Thoracic Endoprosthesis
25-Mar-05	P040024	Medicis Aesthetics Holdings, Inc.	Restylane™ Injectable Gel
30-Mar-05	H030005	CoAxia, Inc.	CoAxia NeuroFlo™ Catheter
01-Apr-05	P040026	Medispec, Ltd.	Orthospec™ Extracorporeal Shock Wave Therapy Device
07-Apr-05	P040034	Confluent Surgical, Inc.	DuraSeal™ Dural Sealant System
12-Apr-05	P040016	Boston Scientific Corporation	Liberte™ Monorail™ and Over-the-Wire Coronary Stent
29-Apr-05	P030037	Biotronic GmbH	Rithron-XR Coronary Stent System
03-May-05	P040023	DePuy Orthopedics, Inc.	Duraloc® Option Ceramic Hip System
14-Jun-05	P040037	W. L. Gore & Associates, Inc.	GORE VIABAHN® Endoprosthesis
21-July-05	P030004	Micro Therapeutics, Inc.	Onyx® Liquid Embolic System (LES)
03-Aug-05	P030036	Medtronic, Inc.	Medtronic® SelectSecure™ Lead Model 3830
03-Aug-05	H050001	Boston Scientific SMART	Wingspan™ Stent System with Gateway™ PTA Balloon Catheter
05-Aug-05	P040021	St. Jude Medical, Inc.	SJM Biocor™ and Biocor™ Supra Valves
10-Aug-05	P040039	Orthometrix, Inc.	Orbasone Pain Relief System
17-Aug-05	P040044	AccessClosure, Inc.	Matrix VSG™ System, Model MX-100
06-Sept-05	P040038	Abbott Vascular Devices	Xact® Carotid Stent System
21-Sept-05	P020016	Walter Lorenz Surgical, Inc.	Total Temporomandibular Joint Replacement System

Expedited Original and Panel Track Supplement PMA Approvals

		COMPANY	DEVICE
22-Oct-04	P040003	InSightec, Ltd.	InSightec ExAblate® 2000
26-Oct-04	P040006	Depuy Spine, Inc.	CHARITÉ™ Artificial Disc
06-Dec-04	P040027	W.L. Gore & Associates	Gore Viatorr TIPS
23-Mar-05	P040043	W.L. Gore & Associates	Gore TAG Thoracic Endoprosthesis
15-Jul-05	P970003/S050	Cyberonics, Inc.	VNS Therapy System

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 1-800-638-2041 or 240-276-3103 directly between the hours of 8:00 a.m. – 5:00 p.m. EST
Fax: 240-276-3101

Part 2 – Reports from ODE Divisions

In the following sections, each of the ODE review Divisions reports on some of their important accomplishments for FY05.

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

Diseases of global impact, such as Severe Acute Respiratory Syndrome (SARS), avian influenza, new strains of *Clostridium difficile*, and the first reported cases of monkeypox in the U.S. require constant vigilance. DAGID staff are frequently involved in efforts to prepare for the potential devastating effects of these diseases, whether they be naturally occurring or the result of bioterrorism. At the same time, the division has implemented new approaches to managing the premarket review process so that we may consistently meet the MDUFMA goals.

- Communicating with the public

DAGID staff are committed to providing the public with up-to-date, scientific information to be used to prepare for crises, such as pandemic flu. Our staff provided significant technical input into the content of CDRH's new Personal Protective Equipment Website. This website, available at www.fda.gov/cdrh/ppe/about.html, provides accurate, easy to understand information for general public and healthcare workers and describes devices that can be used during bioterrorism attacks, influenza pandemics, and other transmissible diseases as well as common questions and answers about personal protection.

- Interacting with government agencies

DAGID staff are also involved in many governmental Interagency Working Groups. We work closely with the Centers for Disease Control and Prevention and the Environmental Protection Agency. Our staff collaborate with our sister public health agencies on issues such as disinfection and sterilization, disease outbreaks, and other emerging public health problems. Some of the topics recently addressed related to Transmissible Spongiform Encephalitis (TSE), appropriate application of disinfectants for device decontamination, and clearance by EPA of surface disinfectants having a TSE claim. We participate in CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC). One of the primary functions of the committee is to issue recommendations for preventing and controlling health care associated infections. DAGID representatives have been instrumental in providing key information regarding regulations regarding medical devices especially those specifically intended to interrupt disease transmission such as sterilants and high level disinfectants and personal protective equipment.

- Maintaining product safety throughout the product life cycle

Through out the past year, DAGID has been involved in a number of important postmarket issues, including recalls of hospital beds, infusion pumps, and catheters. Our experts provided scientific and clinical advice regarding the root causes of these device problems and appropriate corrective actions.

DIVISION OF CARDIOVASCULAR DEVICES (DCD)

Cardiovascular disease continues to be a significant problem for the public health, with cardiovascular devices serving an increasingly important role in the treatment of cardiovascular disease. As a result of this trend, the Division of Cardiovascular Devices (DCD) has become more involved in the development of appropriate technology than ever before. To meet these challenges and the challenge of meeting the MDUFMA goals, we have hired additional staff and streamlined our management of the premarket review process.

- Analyzing trends in pacemakers and ICDs

DCD was interested in analyzing trends in deaths and malfunctions for pacemakers and implantable cardioverter defibrillators (ICDs). We contracted with William Maisel (Cardiovascular Division, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA) to review and analyze PMA annual reports for all pacemakers and ICDs between 1990 and 2002. The study showed that pacemakers and ICDs are generally safe and effective devices, and pointed out that the number of pacemaker and ICD implants has increased substantially. The study also contains two findings that are a source of concern to the FDA: first, the malfunction replacement rate for ICDs is significantly higher than the malfunction replacement rate for pacemakers, and, of perhaps greater concern, is that the ICD malfunction replacement rate appears to be increasing. The study concluded that careful monitoring of the device performance is still required, that the clinical community must continue to report adverse events in a timely manner, and that strategies should be developed to increase the proportion of explanted devices that are returned for manufacturer analysis.

- Work with Heart Rhythm Society

Following a series of implantable defibrillator recalls between May and July of 2005, the FDA co-sponsored a policy conference with the Heart Rhythm Society on September 16, 2005, to bring together stakeholders from the clinical community, industry, patients, and regulators. Discussion focused on the current processes and practices for ensuring reliable products, conducting recalls, and notifying the public of problems. Areas of improvement were identified, and all groups agreed to work together to formulate solutions and create awareness of the issues. In response to these recalls, the FDA created an internal Defibrillator Working Group. This group is tasked with creating a Total Product Life Cycle (TPLC) model for the regulation of defibrillators. Along with

creating a forum for sharing information across Offices, the group is developing guidance documents and operating procedures to facilitate cross-Office decision making, and effective external communication.

- Modeling Cardiac Stent Performance

FDA is providing scientific and regulatory expertise to Stanford Biodesign research aimed at developing simulation models and evaluative imaging technologies to predict cardiovascular and peripheral vascular stent performance. FDA's role is to guide this research so that it results in useful evaluative tool development, and to facilitate the development of ASTM Standards using the information gained from this research. The critical path tools developed from this research could be used to rapidly and inexpensively assess the safety and efficacy of multiple alternative device designs prior to fabrication, physical testing, animal testing and human trials. By the end of 2006, the research team expects to have completed an *in vitro* model of a Superfiscial Femoral Artery stent in motion, and imaging of pediatric patients with aortic coarctation.

- Surrogate Variables Working Group

To stimulate development along the critical path of innovation, the FDA formed the Surrogate Variables Working Group in November 2004, with a collaborative group of individuals including FDA staff, academic statisticians and clinicians. Interest in clinical trials of new drug-eluting stents, a breakthrough technology that has had a substantial impact on patient care, was the initial impetus for the formation of this group and led to DCD's involvement. The goal of the working group is to identify potential uses of surrogate variables in device development, specifically the use of surrogate variables as endpoints for clinical trials intended for regulatory submissions. The mission of the working group will be accomplished by achieving the following three tasks: 1) development of definitions and classifications for surrogate variables; 2) characterization of investigative "tools" to assess the utility of surrogate variables; and 3) identification of appropriate uses of surrogate variables in device clinical trials.

While drug-eluting stent clinical trials may serve as an initial example, the Working Group's aim is to understand the appropriate role of surrogate variables in clinical trials across the field of medical devices. Dissemination of the working Group's efforts will be achieved by submission of manuscripts for publication in peer reviewed journals, and presentation of issues discussed in the Surrogate Variables Working Group in a public forum. Multiple DCD personnel are actively working with other FDA staff, academics, and AdvaMed to accomplish these goals.

DIVISION OF GENERAL, RESTORATIVE AND NEUROLOGICAL DEVICES (DGRND)

The Division of General Restorative and Neurological Devices (DGRND) reviews a wide variety of medical devices, including orthopedic implants, general and plastic surgery devices, physical medical and rehabilitation devices, and therapeutic and diagnostic neurological devices. Our staff have risen to the challenge of maintaining high scientific standards while at the same time, meeting all of the MDUFMA review time goals.

- Leveraging with outside groups

DGRND continues to work closely with industry, academic, clinical and other external groups such as the Orthopaedic Device Forum, the American Academy of Orthopaedic Surgeons, the Orthopaedic Surgical Manufacturer's Association, the Tissue Group, and the Society for Interventional Radiology. For example, our staff have a long-standing collaborative effort with the Orthopaedic Device Forum. The Forum was established to foster an environment of open communication among representatives of the scientific and clinical orthopaedic community, the FDA and other governmental agencies, and representatives of the industry related to musculoskeletal health and diseases. Regularly scheduled meetings of the Orthopaedic Device Forum provide valuable input to DGRND on a variety of topics including clinical trial development, guidance priorities, and voluntary standards.

- Expanding our scientific knowledge base

DGRND staff continually seek opportunities to expand our scientific and clinical knowledge, which greatly enhances our review of innovative technologies. One example is the CDRH Neurologic Devices Interest Group, founded in 2003. The objective of the group is to organize, facilitate, and share education and training opportunities and experiences related to neurologic device products as a means of enhancing and accelerating product review. Each meeting involves staff from across the agency, other government organizations, senior level academic researchers, and clinicians in the biomedical sciences to discuss emerging scientific and medical theory and clinical practice in an informal seminar setting. Outcomes of the Neurologic Devices Interest Group have led to intra- and inter-Center communication and an organized review approach of medical products targeting neurologic disorders and conditions.

- Meeting MDUFMA goals

Over the past fiscal year, the DGRND united as a division to meet all MDUFMA goals. We remain committed to developing guidance documents and reclassifications in all areas of the division to allow for efficient, timely and least burdensome review of all submissions.

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

DOED faced one of its most challenging and exciting years in 2005. The dedicated professionals of our staff assured that the primary mission of our division was achieved and our goals for the year were successfully implemented. Chief among them was the successful implementation of MDUFMA goals and milestones in our premarket review process. Our division personnel take great pride in the timeliness of our decisions and their grounding in sound scientific and regulatory principles. In 2006, we will continue to find ways to improve our review process and to assure timely decisions are reached without compromising public health and safety.

- Outreach to the public and the clinical community

In addition to its focus on meeting our application review times, DOED places a significant emphasis on outreach activities, scientific and regulatory collaborations, and on the development of national and international standards. For example, DOED staff spent a significant amount of time and resources in 2005 reaching out to our stakeholders through a variety of ways including scientific and regulatory publications in peer reviewed journals; writing educational columns in professional and consumer publications; teaching regulatory training courses, conducting seminars and making presentations at professional meetings; developing device specific guidance documents, and developing and updating ophthalmic and ENT device specific websites (e.g., LASIK, Cochlear Implants, Intraocular Lenses (IOLs)) for the general public. DOED believes that the exchange of knowledge and an improved understanding of the regulatory process by consumers, manufacturers, and health care professionals is a critical aspect of our public mission. We look forward to continuing and strengthening our commitment to outreach activities in 2006.

- Building scientific knowledge through collaborative research

In addition to our extensive outreach activities, DOED scientists participate in numerous collaborative studies with stakeholders to improve the premarket review process and to monitor the post approval performance of ophthalmic and ENT devices. DOED staff participate in many ongoing collaborative activities at various levels within the government and extend their collaborative efforts to organizations outside of government as well. Examples of ongoing premarket and postmarket collaborative efforts are described below.

- Driving Simulation Studies

Senior review scientists in DOED are involved in a collaborative study with researchers at the University of Iowa where the National Advanced Driving Simulator (NADS) is located and owned by The National Highway Traffic Safety Administration. The goal of this collaborative effort is to investigate possible correlations between driving performance measures with various ocular and visual tests and measures of the eye. Standard tests of vision used currently in clinical practice are not well correlated to a

person's functional performance. The ultimate objective of the research is to find a surrogate for driving performance as a parameter of functional vision. If successful in our collaborative efforts, FDA review staff as well as ophthalmic device manufacturers will be able to correlate clinical outcomes to a person's functional performance. It is hoped that the development and standardization of this methodology will improve and expedite the evaluation of safety and performance of new ophthalmic devices while reducing testing costs for manufacturers.

- Pediatric Cochlear Implant Studies

Senior review scientists in the Ear, Nose and Throat Branch (ENTB) continue their collaboration with the Center of Disease Control (CDC) in a follow-up study on the cochlear implant pediatric cohort from the 2003 *New England Journal of Medicine* study. The study was published in the February 2006 issue of the journal *Pediatrics* (the study has been posted on the web via PubMed since January 3, 2006 ahead of the print version). The results of this study show that the children implanted with a cochlear implant with a positioner continue to be at increased risk for bacterial meningitis beyond 2 years post-implantation. These findings support the continued close monitoring of implanted patients and adherence to the safety precautions outlined by healthcare providers and parents/caretakers of children with cochlear implants, particularly among children with a positioner. It is still unknown whether the risk of meningitis in pediatric patients whose implants have positioners might be reduced if the implant were removed or replaced by a model that does not have the positioner. Any potential benefits of explantation surgery must be carefully weighed against the risks for operative complications, including perioperative meningitis. The present study concludes that there is currently insufficient information to support a recommendation for elective surgery to explant devices with a positioner.

- International Club for Biomaterials and Regenerative Medicine in Ophthalmology

DOED review scientists are active participants and have a leadership role in the International Club for Biomaterials and Regenerative Medicine in Ophthalmology (ICBRO). ICBRO was originally founded in Europe to promote interdisciplinary cooperative work by bringing together on an international level ophthalmic scientists, engineers and clinicians to advance the quality of existing devices by improving or creating new materials and test methods to assess those materials, and to develop new biocompatible, biodegradable materials useful for regenerative medicine in ophthalmology. The 2006 meeting will be the second meeting in the U.S. and will focus on advances in materials and testing for IOLs, contact lenses, glaucoma devices and retinal implants.

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

The Division of Reproductive, Abdominal and Radiological Devices has worked to meet our MDUFMA and non-MDUFMA deadlines as well as to maintain our involvement in other activities, e.g., guidance development, postmarket review, standards-setting, and professional development. The following are two important recent DRARD activities.

- Pilot program to incorporate epidemiology expertise

From February 2002 through December 2004, DRARD participated in an epidemiology pilot program with the Office of Surveillance and Biometrics (OSB). Twenty-eight of our staff worked with epidemiologists, safety analysts, and statisticians from OSB on first-of-a-kind PMAs to design postapproval studies. We developed standard operating procedures and epidemiology review templates; integrated epidemiologists into the premarket review team process; utilized available marketing data as analyzed by safety analysts; established new processes for capturing postmarket information; furthered the training of epidemiologists in premarket review procedures and presentations at Advisory Panel meetings; and developed evaluation instruments to assess the value added by the piloted processes. The success of the pilot in DRARD has led CDRH management to expand the program across all ODE divisions for first-of-a-kind PMAs.

- Improving procedures for Industry meetings

To assist firms in their interactions with us, DRARD has worked to improve the timeliness, efficiency, and productivity of our meetings. To accomplish these goals, the Division developed new meetings procedures. At the time of a meeting request, as a first step in the process, the Division asks for 10 copies of a meeting background package. Receipt of the background package will trigger the second step in the process, the prompt scheduling (usually within 45 days) of our internal pre-meeting and the meeting with the sponsor. We believe this two-step process enhances timeliness and efficiency for several reasons: first, the requestor will be able to prepare a background package on a time schedule that meets his/her needs; second, the Agency will have adequate time to review fully the background package and prepare for the formal meeting; third, good preparation on everyone's part will enhance information exchange and productivity; and finally, the process should help to eliminate the need to re-schedule meetings due to incomplete preparation on the part of either party. Our project manager can provide additional suggestions on how to maintain open and effective communications between our Division and our stakeholders.

- Outreach to scientific and clinical community

The staff has remained actively involved in outreach to the scientific and clinical communities. Members of the Obstetrics and Gynecology Devices Branch (OGDB) have met with the American College of Obstetricians and Gynecologists (ACOG) clinical

practice committees on device issues of interest including “keepsake videos,” fetal monitors, and condom labeling. DRARD staff has also continued interactions with NIH researchers regarding technologies for detection and diagnosis of cervical disease. We have established an ongoing series of conferences with NCI to discuss Pap tests and cervical screening.

Members of the Gastroenterology and Renal Devices Branch (GRDB) organized a meeting of the Gastroenterology and Urology Devices Advisory Panel on June 8, 2005, to discuss general issues related to the premarket requirements for the safe and effective use of hemodialysis equipment labeled for nocturnal home hemodialysis (NHHD) therapies. The panel members provided recommendations on monitors and alarms for the sleeping patient, quality of water at home, study design for small clinical trials, and training on how to use the device properly.

Part 3 – Magnet for Excellence

In ODE, our staff is our most valuable resource. We are very proud of the accomplishments of our highly trained and dedicated staff of scientists, engineers, physicians, nurses, and other health professionals. ODE staff are routinely asked to participate and lead government working groups and consensus standards committees, to present at professional conferences and at academic institutions, and to prepare articles for publication in journals and other publications. This past year posed difficult challenges to the U.S. in the wake of Hurricanes Katrina and Rita. ODE staff who are commissioned officers in the Public Health Service responded and many were deployed to serve critical needs in the nation's public health system.

The complete list of publications and presentations by ODE staff are given in Appendix B and the complete list of all ODE staff who serve as liaisons to standards committees is also in Appendix B. A few highlights of our activities are described below.

ODE Staff Receive Outside Honors

Several ODE staff members were honored this past year with awards from outside organizations.

Kish Chakrabarti of DRARD was named as one of the 100 physicians, administrators and thought leaders in the June issue of *Health Imaging & IT*.

Several ODE staff were honored by awards from the ASTM Committee on Medical and Surgical Materials and Devices (F04). **John Goode** of DGRND was awarded the 2005 LeRoy Wyman Award for outstanding contributions as an engineer, **Vivianne Holt** of DCD was awarded the 2005 Robert Fairer Award for her work on the Interventional Cardiology Task Group, and **Mark Melkerson** of DGRND received the 2005 Patrick G. Laing Award for distinguished service and outstanding technical contributions.

An article recently published by **Malvina Eydelman** and **Bruce Drum** of DOED entitled "Systematic evaluation of wavefront-guided outcomes" has been selected as one of the most important papers recently published in *Ophthalmology* by OphthoLinx Refractive / Eye Surgery Newsletter as well as by Optics/Refraction/Lenses Newsletter.

Humanitarian Efforts

Many of our staff were called upon to assist the nation during this past year of significant and devastating national disasters. Several ODE staff were deployed to help in the Gulf area to care for victims of Hurricanes Katrina and Rita. In addition to helping in direct patient care, ODE staff also helped to set up systems to care and manage the large number of patients needing services, as well as assessing infrastructure needs for

health care and handling logistics for the large number of PHS officers being deployed to the area. In addition to disaster relief, ODE PHS officers also provided aid and services for Native Americans as well as for international relief efforts.

The ODE PHS officers deployed over the past year were:

Name	Division
LCDR Brian Lewis	DCD
LCDR Nina Mezu-Nwaba	DCD
CDR Victoria Hampshire	DCD
CAPT. Bette Lemperle	DCD
CDR Stephen Rhodes	DGRND
CDR Samie Allen	DGRND
CAPT. Susan Runner	DAGID
LT Scott Colburn	DAGID
LT Mary Brooks	DAGID
LCDR Lori Austin-Hansberry	DOED
LTJG Brad Cunningham	DOED
LCDR Nicole Wolanski	POS
CAPT. Paula Simenauer	POS

Standards

ODE staff continue to play a significant role in both domestic and international standards committees. Our staff members are liaisons and often, chairpersons of standards committees for a wide range of devices for a variety of standards organizations including ISO, AAMI, ASTM, ANSI and IEC. ODE is committed to the standards development process, and we believe that the development of scientifically sound standards will allow us to efficiently review premarket applications for both existing and innovative technologies. A complete list of ODE staff involved in standards activities is in Appendix B.

International Outreach

In FY 05, ODE staff continued our efforts in international outreach and harmonization. Several of our staff members serve on the Global Harmonization Task Force, an effort to standardize and harmonize medical device regulation around the world. Our office also hosted fellow regulators from around the world, including representatives from Korea, Finland, Canada, and Taiwan to share information and our experiences in medical device regulation.

Part 4 – Major Program Initiatives

PILOT PROGRAM FOR ASSESSING THE QUALITY OF PREMARKET REVIEWS

As part of CDRH's continuing efforts to assess performance, ODE led a cross-office pilot program during FY 05 to begin the assessment of the quality of reviews. The program began by looking at how the reviews of three scientific elements common to many Premarket submissions - biocompatibility, sterility/packaging, and statistics – were documented in FDA review memos. Three teams with expertise in each scientific area were assembled from across CDRH. Each team created a set of elements which they felt were critical for documentation or inclusion in a review related to that area. Those items were then used to assess the quality of review memos from randomly selected 510(k) and PMA submissions with final decisions. Each team was tasked with completing two rounds of review during FY 05 – each round consisting of 25 510(k) and 2 PMAs.

For 510(k)s, significant quality issues were found in 28% of biocompatibility reviews and 78% of sterility reviews. For the PMAs, no major issues were noted for the biocompatibility reviews but inadequacies in sterility reviews were noted in all. Statistical review memos were evaluated in 4 PMAs and were deemed adequate in all the reviews.

The findings of the pilot program will be used to implement educational and procedural changes during FY 06 with the intent of improving the quality of the reviews for these elements. The three groups will continue to perform regular assessments of submissions to monitor changes. In addition, a fourth team will begin assessing the quality of software reviews in FY 06.

CHANGE IN POST-APPROVAL STUDY PROGRAM

January 2005 brought a major shift in the program related to post-approval studies (PAS) ordered as conditions of approval (CoA) for PMAs. Traditionally, this program had been the responsibility of ODE. Beginning on January 1, ODE formally began consulting epidemiologists in the Office of Surveillance and Biometrics (OSB) for novel or first-of-a-kind PMAs at the time of submission. The epidemiologists have been tasked with reviewing the PMA data with an emphasis on potential clinical issues that would be appropriate for post-market evaluation. Early involvement of the epidemiologists allows time to begin interaction with the other review team members and the sponsor to identify the issues as well as to begin designing an appropriate PAS protocol. In FY 05, epidemiologists were consulted and included on the review team for 11 new PMA submissions and made several presentations to Advisory Panels. For PMAs which are not first-of-a-kind submissions, ODE will maintain primary responsibility for working with the sponsor in formulating an appropriate PAS. Also beginning in January of 2005, OSB assumed responsibility for tracking all PAS ordered as a CoA.

An electronic database which will allow CDRH to notify sponsors if and when PAS reports are overdue was created and became operational. OSB will also post and update the status of PAS requirements on the public website. OSB will now be responsible for reviewing PAS interim/final reports and issuing the appropriate letters with consults from ODE staff and reviewers as needed. These efforts will continue in FY 06 and the Center believes they will result in PAS which are well designed, better tracked, and more likely to be performed and completed.

LEVERAGING IT SYSTEMS FOR INCREASED EFFICIENCY

Over the past year, ODE has continued to pursue development of new IT systems for improved tracking and monitoring of submissions. We have begun to critically review our current systems and to consider the infrastructure needs required to move toward electronic submissions.

- Electronic Copies

ODE encourages all manufacturers to submit electronic copies along with the paper submission whenever possible. Electronic copies will save resources for the FDA and will provide additional navigational tools for the review staff who will be working with the document. In addition, the electronic copy may serve as one of the required paper copies. 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.

- Improved Systems For Document Tracking And Archiving

Numerous enhancements were made to information systems used by ODE during FY 2005. Image2000 (an archival document management system) received a new eReviewer interface that allows for viewing My Favorites, folder contents, folder summary information and a document content all at the same time. The Enhanced Center Information Retrieval System (eCIRS), a web-based retrieval system, gained added functionality and enhanced data access and reporting. The Center Tracking System (CTS), formerly DTS, has new features, including a system for tracking Condition of Approval studies, a mechanism for the development of new product codes, and the ability to calculate MDUFMA cycle days for PMAs, modular PMAs and amendments.

Work is underway on an improved system for tracking consulting reviews across CDRH, called the eConsult system, which will be accessed through the existing CTS. We have also recognized the need to optimize and modernize CDRH premarket administrative processes and the supporting IT architecture and systems. A Center-wide group has been working with a contractor to address current inefficiencies in the databases used

in the processing of Premarket Applications and will be initially developing the reporting and linking capabilities before phasing in other capabilities, including post market administrative processes.

- Improved Communication and Interaction Tools For PMA Review Teams

In FY 05, ODE continued to pilot the use of eRoom, web-based software to facilitate communication and interactions among team members in the review of PMAs. The software was first 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 were assessed and a decision was made to expand the use of the software to encompass all original PMAs and panel track PMA supplements received from FY 06 onward. The benefits of the program include improved communication among review team members and improved consistency by providing a central storage location for documents. It is hoped that the software will lead to improved timeliness of reviews. The eRoom software is also used by other working groups and teams within ODE for collaboration, document creation, and document posting in a shared work space.

- Hardware Upgrades

Using Center funding, ODE replaced 40% of its desktop computers with laptop/docking station computers as part of a Center plan to update computers on a regular basis. In addition, ODE improved its infrastructure by ordering new network printers and scanners.

COMBINATION PRODUCTS

Combination products, consisting of devices and drugs or devices and biologics, continued to be a focus of effort for ODE. In FY 05, we interacted with the FDA Office of Combination Products, the Center for Drug Evaluation and Research (CDER), and the Center for Biologics Evaluation and Research (CBER) on the review of many combination device-drug and device-biologic products.

In FY 05, ODE reviewed 20 Requests for Designation (RFDs), 13 for device-drug combinations and 7 for device-biologic combinations. CDRH was given the lead for 10 of these. We also reviewed and acted on 109 premarket applications for combination

products. Our device expertise was called upon frequently by our sister centers and we performed 194 consulting reviews.

Our staff is involved in many intercenter collaborative working groups, including:

- Cardiovascular Products Working Group
- Cartilage Repair Group
- DHHS Joint Working Group on Telemedicine
- FDA RFID Team
- Interagency CWD Decontamination Working Group
- Interagency Oncology Task Force
- Orthopedic Indications Working Group
- Patient Reported Outcomes Intercenter Group
- Rheumatology Intercenter Working Group
- Tissue Engineering Working Group (FDA, NIH, NIST, NASA, DOE)
- Tissue Policy Team
- Tissue Reference Group
- Wound Healing Clinical Working Group
- Wound Care Solutions Working Group

ODE Device Guidance Documents

In FY 05, ODE issued 14 guidance documents, 5 Level 1 and 9 Level 2, which are listed below. Among the 14, 5 are Special Controls guidance. In addition to consulting with all of the offices across the Center on many issues addressed in guidance, one of the 14 was developed in collaboration with Office of In Vitro Diagnostics and another in collaboration with the Office of Compliance. 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; fax 240-276-3103; Email dsmica@cdrh.fda.gov or write to DSMICA (HFZ-200, Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307.)

Document Name	Off/Div/Br	Date	Links
Guidance for Industry and FDA Staff - Class II Special Controls Document: Oral Rinse to Reduce the Adhesion of Dental Plaque	ODE/DAGID/DEDB	09/20/2005	Text PDF
Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff	OIVD ODE	08/12/2005	Text PDF
Guidance for Industry and FDA Staff - Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)	ODE/DRARD/OGDB	07/27/2005	Text PDF
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff	CBER OIVD ODE	05/11/2005	Text PDF
Dental Bone Grafting Material Devices - Class II Special Controls Guidance Document - Guidance for Industry and FDA Staff	ODE/DAGID/DEDB	04/28/2005	Text PDF
Guidance for Industry and FDA Review Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)]	ODE/DAGID/GHDB	04/15/2005	Text PDF
Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software	ODE OC	01/14/2005	Text PDF
Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems - Guidance for Industry and FDA Staff	ODE/DCD/PVDB ODE/DCD/ICDB	01/13/2005	Text PDF
Vascular and Neurovascular Embolization Devices - Class II Special Controls Guidance Document - Guidance for Industry and FDA Staff	ODE/DRARD/OGDB ODE/DGRND/PRSB ODE/DCD/PVDB	12/29/2004	Text PDF
Class II Special Controls Guidance Document: External Penile Rigidity Devices	ODE/DRARD/ULDB	12/28/2004	Text PDF
Class II Special Controls Guidance document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information - Guidance for Industry and FDA Staff	ODE/DAGID/GHDB	12/10/2004	Text PDF
Clinical Trial Considerations: Vertebral Augmentation Devices to Treat Spinal Insufficiency Fractures - Guidance for Industry and FDA Staff	ODE/DGRND/REDB ODE/DGRND/ORDB	10/24/2004	

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.

Final Classification Actions

- Published a final rule classifying external penile rigidity devices intended to create or maintain sufficient penile rigidity for sexual intercourse into class II (special controls). FDA is also exempting these devices from premarket notification requirements. [Effective January 27, 2005].

Final Reclassification Actions

- Published a final rule in the *Federal Register* on December 29, 2004 reclassifying two embolization device types from class III into class II (special controls). The vascular embolization device (previously the arterial embolization device) is intended to control hemorrhaging due to aneurysms, certain type of tumors, and arteriovenous malformations. The neurovascular embolization device (previously the artificial embolization device) is intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations. [Effective January 28, 2005].

- Published a final rule in the *Federal Register* on April 28,2005 reclassifying tricalcium phosphate (TCP) granules for dental bone repair from class III into class II (special controls), classifying into class II (special controls) other bone grafting material for dental indications, and revising the classification name and identification of the device type. Bone grafting materials that contain a drug that is a therapeutic biologic will remain in class III and continue to require a premarket approval application. The classification identification includes materials such as hydroxyapatite, tricalcium phosphate, polylactic and ploglycolic acids or collagen. [Effective May 31, 2005].

Part 5 – Key Performance Indices

Historically, the ODE Annual Report has included combined data for both ODE and OIVD. This FY 05 Annual Report is the first report that includes only data for ODE. In this part, first, we present the major submissions[1] received in ODE from FY 95 to FY 05. For these submissions (known as "the receipt cohort"), we provide our review performance for Premarket Approval Applications (PMAs), PMA supplements, Premarket Notifications (510(k)s), Investigational Device Exemptions (IDEs), Humanitarian Device Exemptions (HDEs), and Request for Information (513(g)s). For PMAs and 510(k)s, in addition to review performance data, we also provide our progress toward meeting MDUFMA performance goals. In the remainder of this part, we provide information on the number of major submissions processed in FY 05 (known as "the decision cohort").

Major Submissions Received

As shown in Table 1, during FY 05, ODE received 8,714 major submissions, up from 8,536 in FY 04. This increase is primarily due to an increase in the total number of PMA supplements received.

Of the 43 original PMAs and 12 panel track supplements received in FY 05, 5 were granted expedited status. In contrast, 14 original and PMA panel track supplements received expedited status in FY 04. In FY 05, 16 of the 43 (37%) original PMAs were submitted as modular PMAs as compared to 21 (57%) modular PMAs submitted in FY 04.

Of the 712 PMA supplements received in ODE in FY 05, 169 were categorized as 180-day PMA supplements, down from 235 in FY 04. The number of fee paying 180-day supplements, however, remains fairly stable between FY 05 (93) and FY 04 (97).

A total of 184 requests were received and processed for real-time PMA supplements in FY 05, slightly up from 178 in FY 04. Of those submissions, 132 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 (56%) followed by DGRND (16%), DOED (14%), DRARD (11%), and DAGID (3%).

In addition to 180-day and real-time supplements, CDRH also received 281 30-day notices/135-day supplements in FY05, a significant increase from the number of 30-day notices/135-day supplements received in FY 04 (135). This increase is primarily due to an increase in the number of manufacturing changes associated with cardiovascular devices.

Of the 3,130 510(k)s received in FY 05, 2,299 were submitted as traditional 510(k)s, 130 were submitted as abbreviated 510(k)s, and the remaining 701 were Special 510(k)s.

[1] A major submission is defined as an original statutory premarket application that requires FDA's scientific review and decision.

When compared to the 3,107 510(k)s received in FY 04, the numbers of 510(k)s received for each category remains fairly stable (2,279 traditionals, 110 abbreviated, and 718 Specials). One 510(k) was granted expedited status in FY 05.

ODE continues to see an increase in the number of 513(g)s received each year. A 513(g) is a request for information regarding FDA regulatory requirements applicable to a device. Three hundred and thirteen 513(g)s were received in FY05, a 14% increase in the number of 513(g)s received in FY 04 and double the number received in FY 03.

ODE received approximately the same number of original IDEs and IDE supplements between FY 04 and FY 05. In FY 05, ODE received and processed 226 original IDEs and 4,262 IDE supplements as compared to 222 original IDEs and 4,298 IDE supplements in FY 04.

In FY 05, the number of original HDEs received was 4, down from 9 in FY 04. The number of HDE supplements received also decreased slightly from 28 in FY 04 to 24 in FY 05.

Table 1. Major Submissions Received
FY95 – FY05

TYPE OF SUBMISSION	1995 ODE& OIVD	1996 ODE& OIVD	1997 ODE& OIVD	1998 ODE& OIVD	1999 ODE& OIVD	2000 ODE& OIVD	2001 ODE& OIVD	2002 ODE& OIVD	2003 ODE& OIVD	2004 ODE Only	2005 ODE Only
Original PMAs	39	44	66	48	64	67	71	49	54	37	43
PMA Supplements	499	415	409	517	557	546	641	645	666	565	712
Original IDEs	214	253	297	322	304	311	284	312	242	222	226
IDE Supplements	3,171	3,189	3,776	4,277	4,127	4,388	4,811	4,724	4,415	4,298	4,262
510(k)s	6,056	5,297	5,049	4,623	4,458	4,202	4,248	4,320	4,247	3,107	3,130
Original HDE	0	0	4	8	12	11	5	5	10	9	4
HDE Supplements	0	0	0	0	4	10	16	16	29	28	24
513(g)s		2	29	34	43	59	82	104	156	270	313
Total	**9,979**	**9,200**	**9,630**	**9,829**	**9,569**	**9,594**	**10,158**	**10,194**	**9,819**	**8,536**	**8,714**

ODE Review Performance

- Premarket Approval Applications (PMAs)

The figures below provide the ODE review performance for PMAs filed in FY 01 to FY 04. The data for FY 05 was not included because a significant number of PMA submissions received in FY 05 are still under review and a final decision has not been issued. (The data for FY 05 will be presented in the next ODE annual report.)

As shown in Figure 1 below, the average total FDA review time for all original PMAs and panel track PMA supplements from filing to approval has improved. Likewise, the average total elapsed time from filing to approval for the "receipt cohort" has decreased from 376 days in FY 01 to 290 days in FY 04 (see Figure 2).

Figure 1: Average Total FDA Review Days from Filing to Approval (excluding withdrawals) for All Original and Panel Track PMA Supplements

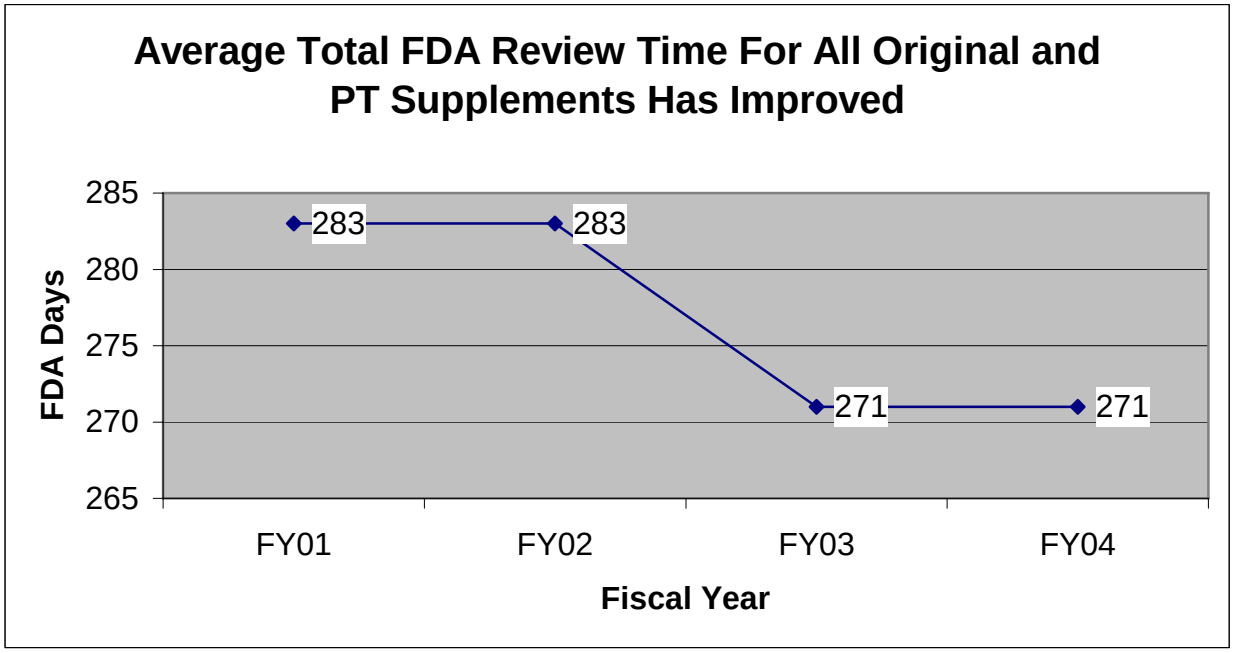


Figure 2: Average Total Elapsed Days from Filing to Approval (excluding withdrawals) for All Original and Panel Track PMA Supplements

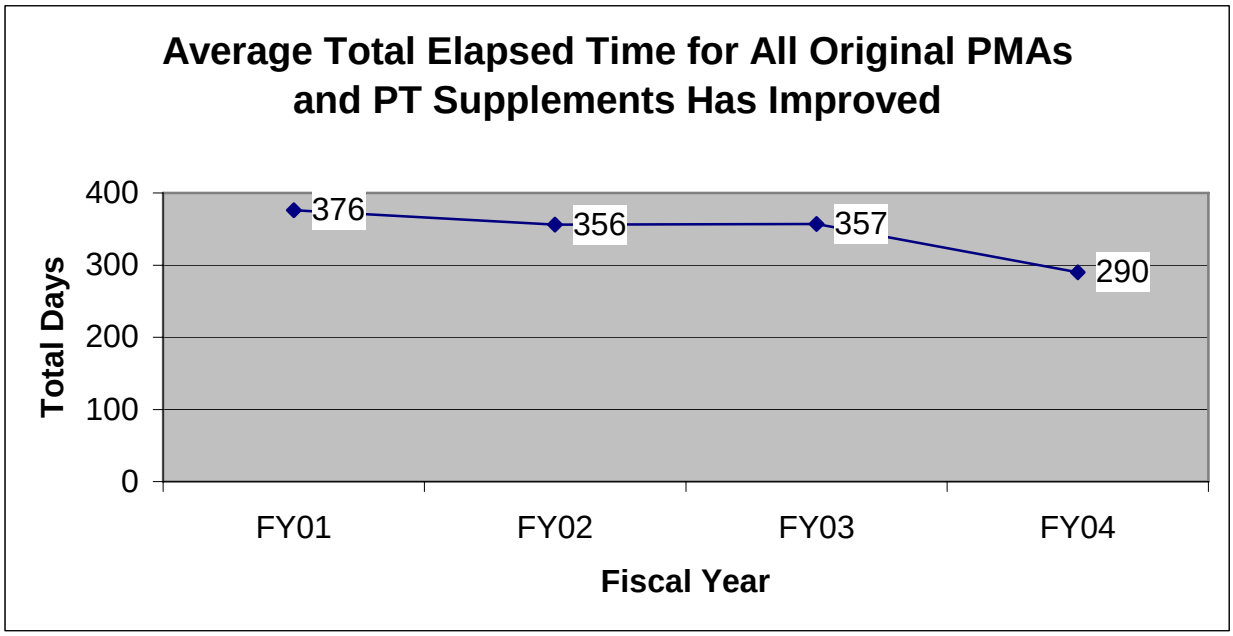
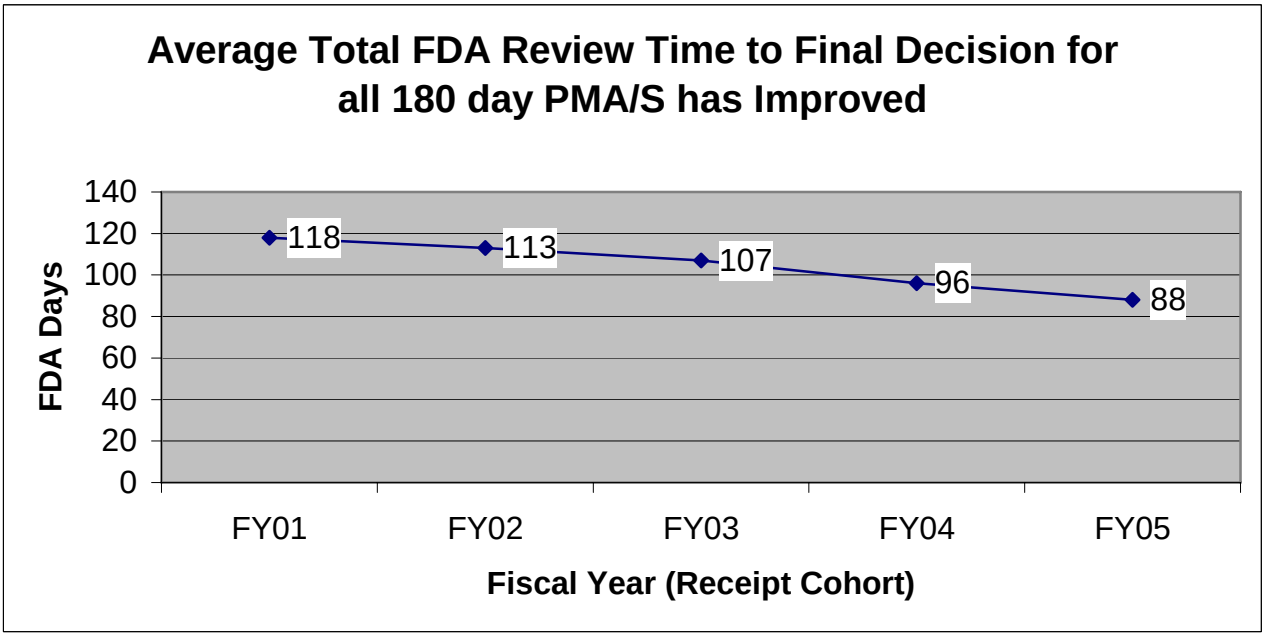


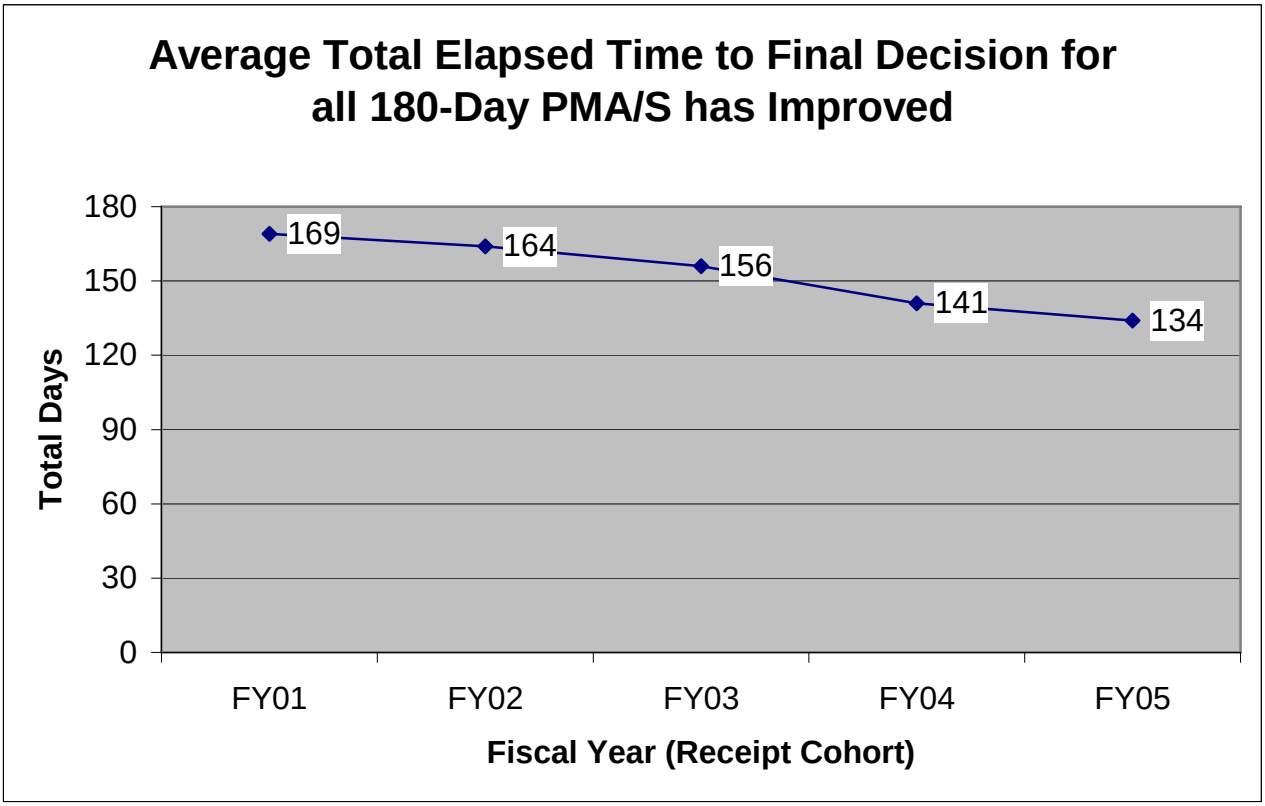
Figure 3: Average Total FDA Days from Receipt to Final Decision for all 180-day PMA Supplements –



As shown in Figure 3, the average ODE review time from receipt to final decision (i.e., approvals and other final decisions such as withdrawals and conversions) for 180-day PMA supplements has continued to trend downward. For the FY 05 receipt cohort, the average ODE review time was 88 days, down from 107 days in FY 03.

Similarly, there has been significant improvement in the average total elapsed time for 180-day PMA supplements. For the FY 05 receipt cohort, the total time was 134 days, down from 156 days in for the FY 03 receipt cohort (see Figure 4).

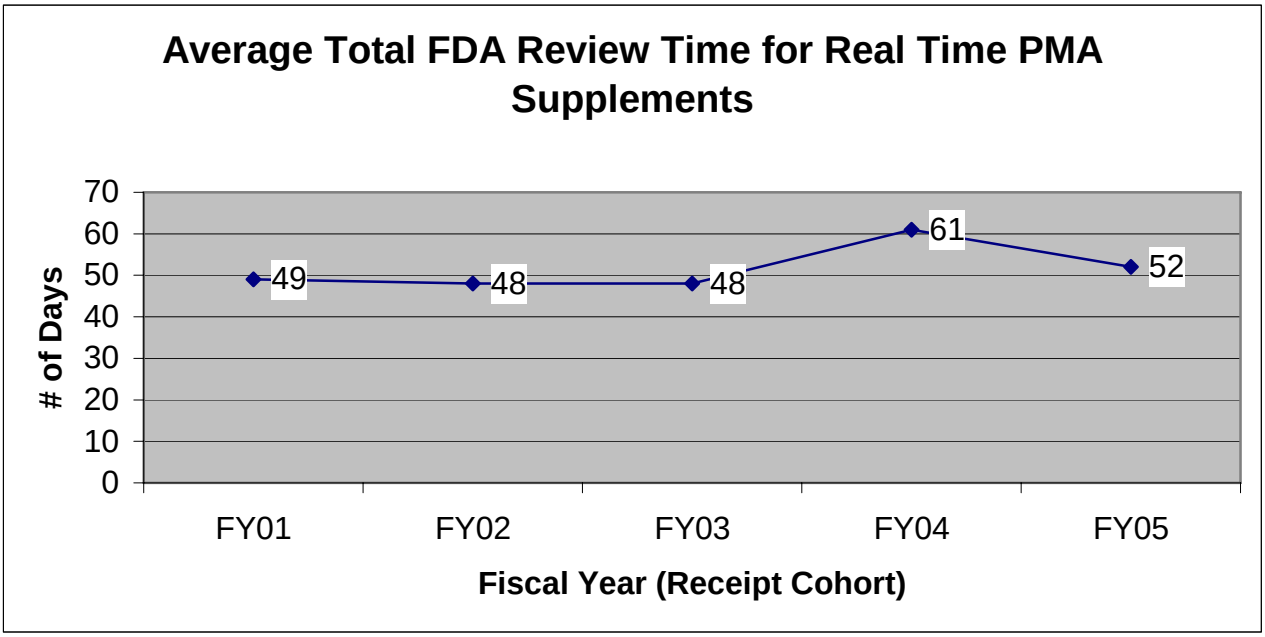
Figure 4: Average Total Elapsed Days from Receipt to Final Decision for all 180-day PMA supplements.



With the exception of FY04, the average total FDA review time from receipt to final decisions (i.e., approvals and other final decisions such as withdrawals and conversions) for real-time supplements has remained fairly constant at approximately 50 days (see Figure 5). Since the average review cycle for a real time PMA supplement is one cycle, the average FDA review time is approximately the same as the average total elapsed time. MDUFMA has resulted in a significant increase in the number of real-time

supplements received by CDRH. In FY 05, ODE received 182 real-time supplements, as compared to 138 received in FY 02, an increase of 32%.

Figure 5: Average Total FDA Review Time for Real Time PMA Supplements



- Product Development Protocols (PDPs)

No original PDPs were approved in FY 05. One routine PDP supplement and one Real-Time PDP Supplement were "approved." Note that a PDP that has been "declared complete" is considered to have an approved PMA.

- 510(k) Review Performance

As shown in Figure 6, the average FDA review time from receipt to final decision has steadily declined from FY 01 through FY 05. For FY 05, the average ODE review time was 49 days, down from 64 days in FY 04. Similarly, the average total elapsed time decreased from 92 days in FY 04 to 69 days to FY 05 (Figure 7).

Figure 6: Average FDA Time From Receipt To Final Decision

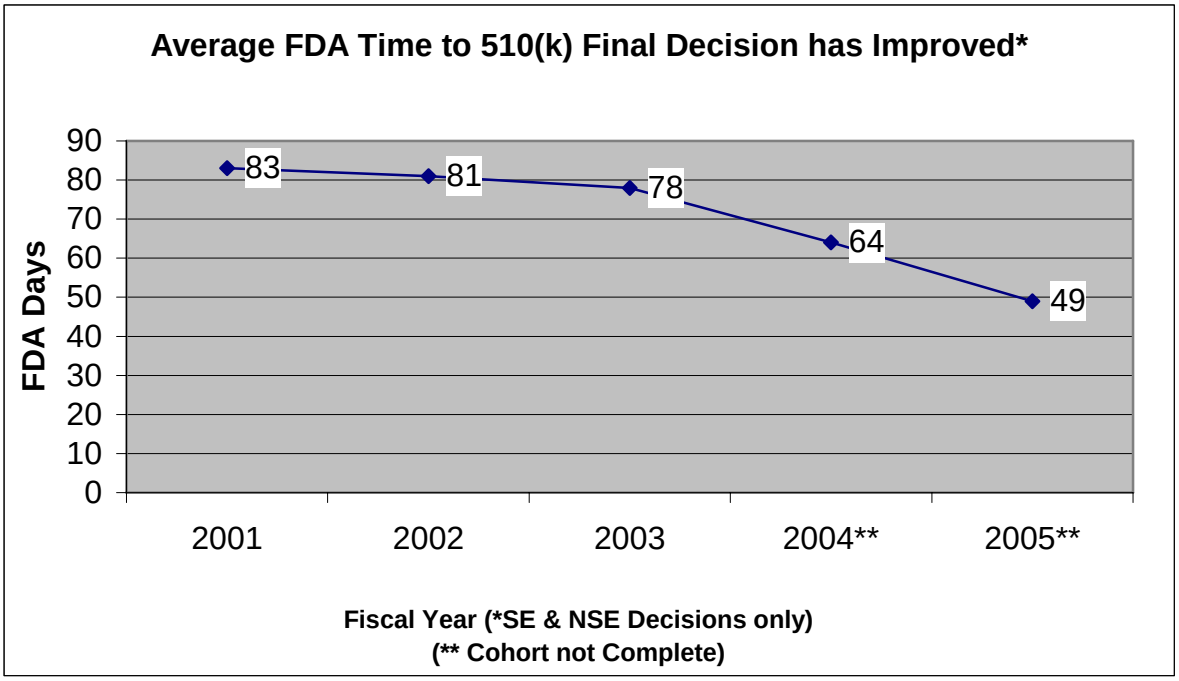
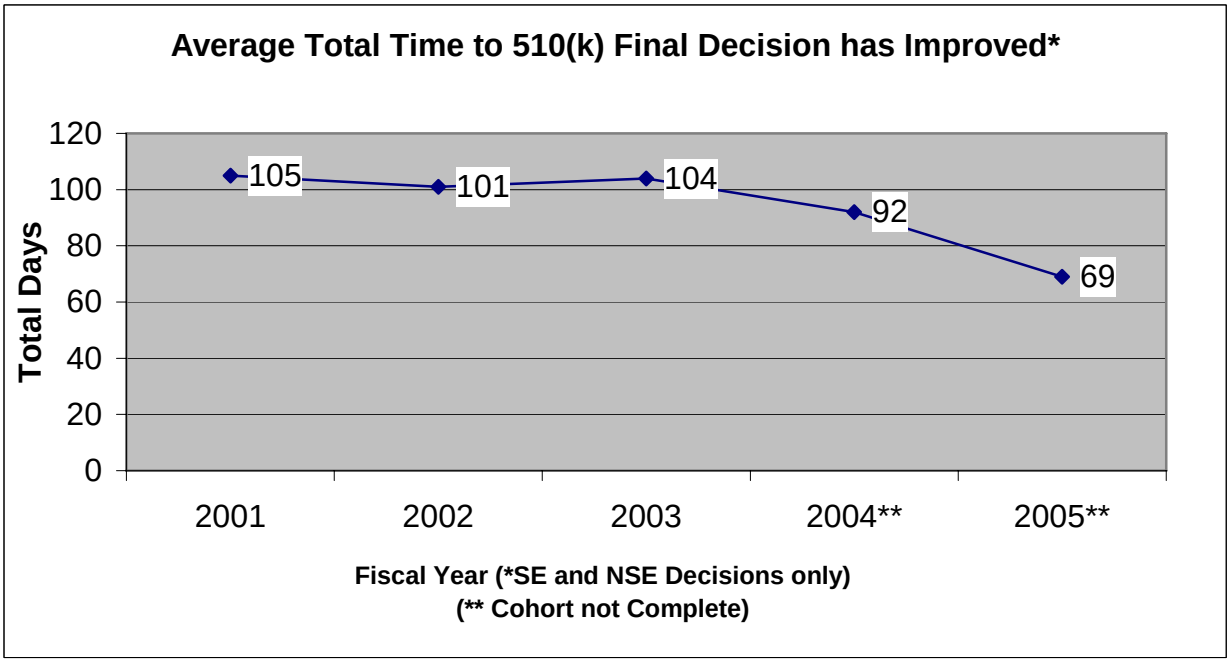


Figure 7: Average Total Elapsed Time From Receipt To Final Decision



- Third-Party Review of 510(k)s

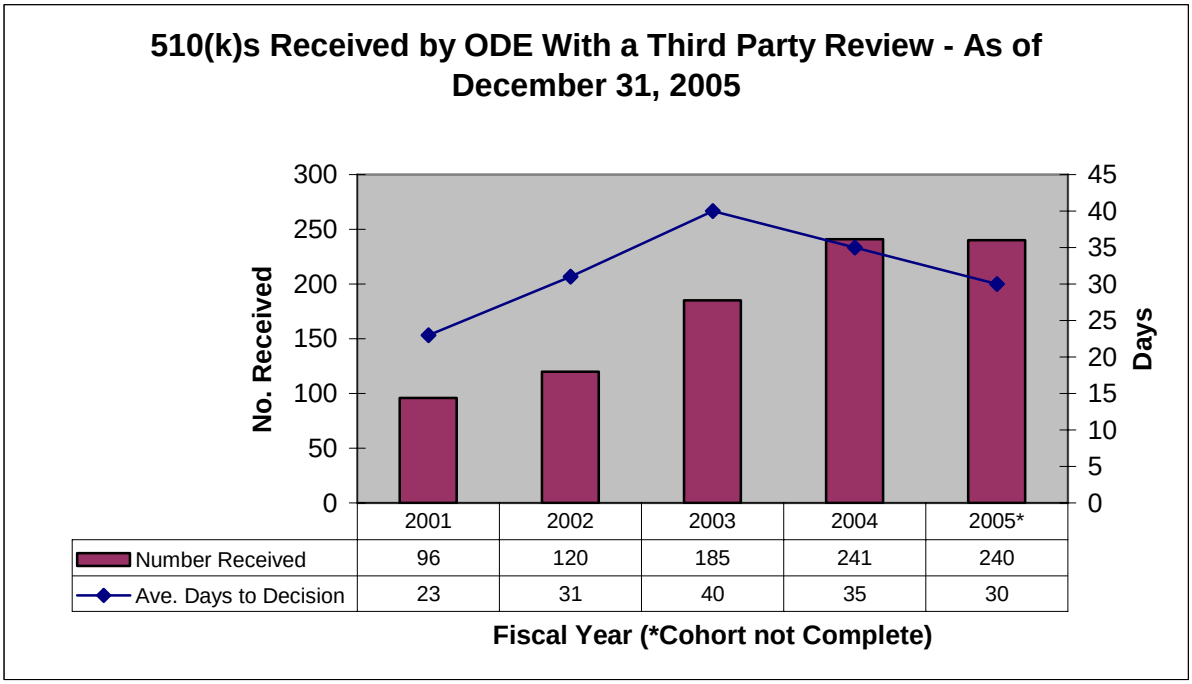
During FY 05, ODE received 240 510(k)s reviewed by third-party organizations under the Accredited Persons provisions (Section 523) of the Federal Food, Drug, and Cosmetic Act.

The average days from the time FDA received the completed 510(k) from the third-party reviewer to the time FDA issued the final decision to the 510(k) holder has decreased from 35 days in FY 04 to 30 days in FY 05.

CDRH continued to take steps during FY 05 to improve the quality and consistency of third-party reviews and facilitate timely CDRH action on these submissions. CDRH conducted a training session for ODE/OIVD staff on October 22, 2004 in Rockville, Maryland, and for third-party reviewers on October 26-27, 2004 in Gaithersburg, Maryland. CDRH also conducted telephone conferences with all third-party organizations in January and April 2005 to provide a routine forum for discussing issues and answering questions.

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

Figure 8: 510(k)s Received By ODE with a Third Party Review*



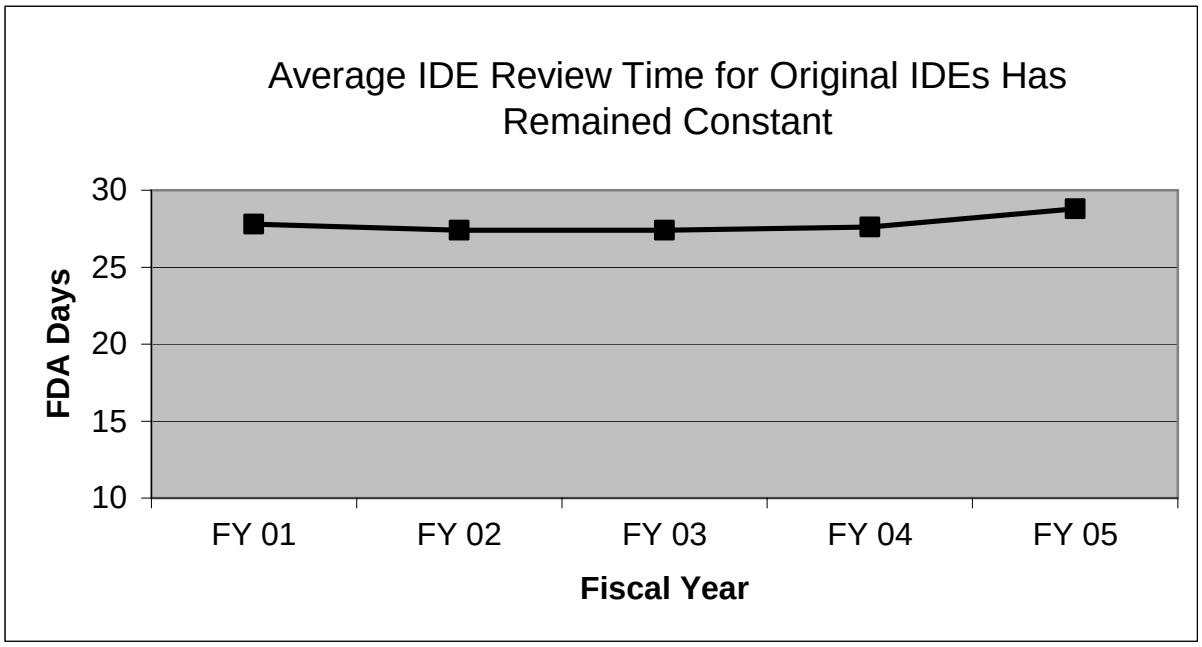
- Humanitarian Device Exemption (HDE) Applications

ODE received 4 original HDEs in FY 05. Three were still under review at the end of FY05 and one was approved. The total FDA review time for the HDE approval was 181 days.

- Investigational Device Exemptions (IDE) Applications

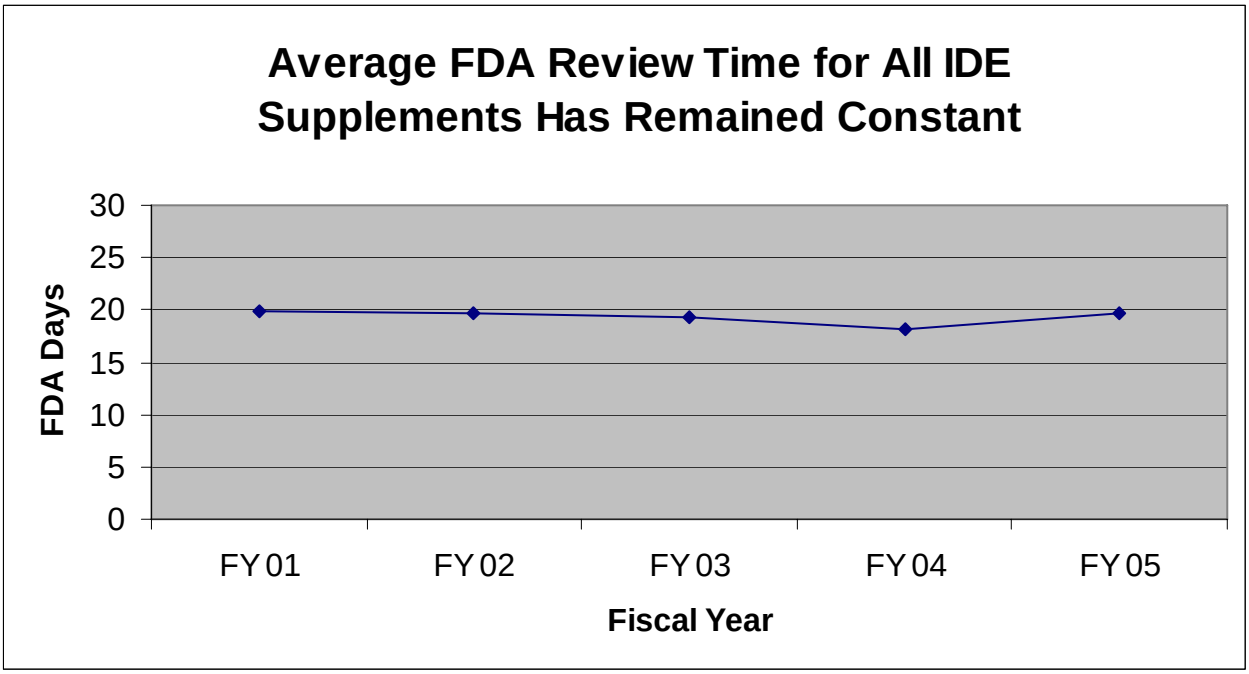
In FY 05, ODE received 226 original IDEs. There were 238 decisions made on original IDEs. One hundred percent of all original IDE decisions were issued within 30 days in FY 05. The average review time was 29 days.

Figure 9: Average FDA Review Time For Original IDEs



In FY 05, 100% of the IDE supplements received were reviewed within the 30-day statutory timeframe. The average review time for IDE supplements slightly increased from 18 to 20 days.

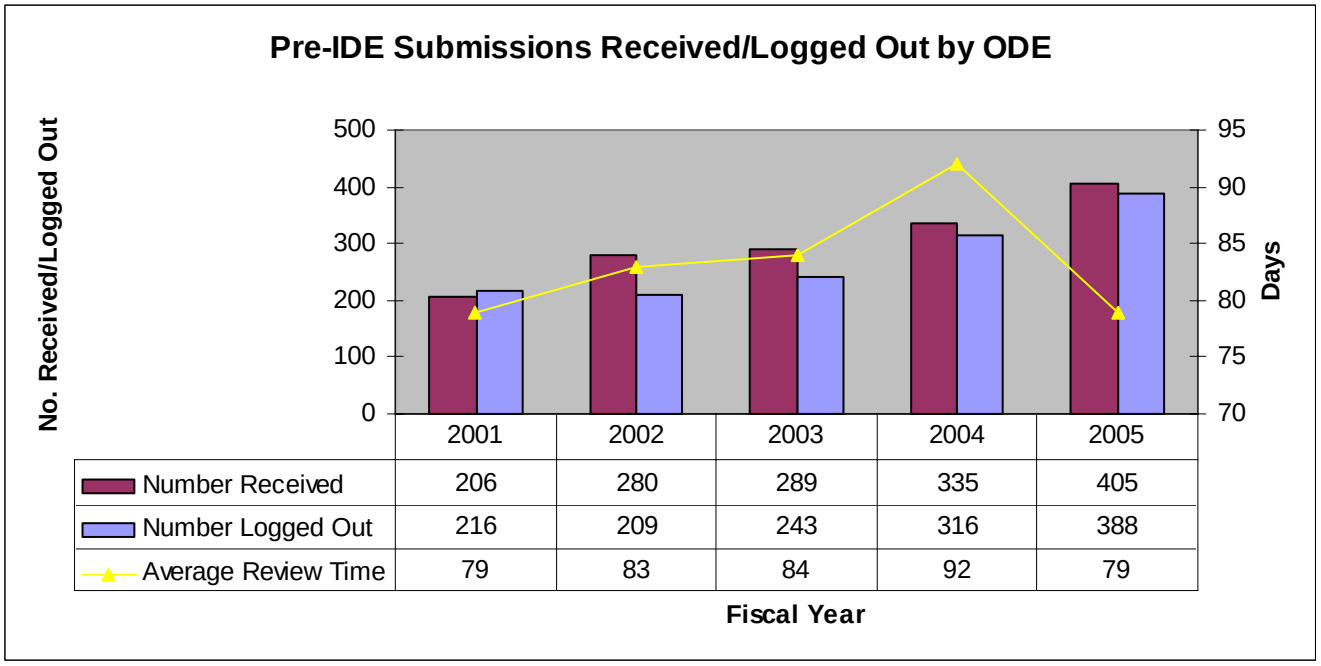
Figure 10: Average Total FDA Review Time for All IDE Supplements



- Pre-IDE Submissions

During FY 05, ODE received 405 pre-IDEs. Based on these reviews, guidance for the pre-original IDE submissions were provided to the sponsors through meetings with the sponsors, letters, fax, or by phone. The number of pre-IDE submissions has increased steadily every year due primarily to increasing awareness of the existence and usefulness of the program, as well as increasingly complex devices and combination products. Review times for pre-IDEs have stayed about the same over the period of FY 01 through FY 05 despite significantly increased demands on the program.

Figure 11: Pre-IDE Submissions and Average Review Days



Performance on MDUFMA Goals

FDA provides regular updates on MDUFMA performance and these reports are available at the following website: www.fda.gov/cdrh/mdufma. Overall, ODE has made excellent progress in implementing MDUFMA and is achieving nearly all of the performance goals. CDRH has worked hard to communicate the new requirements and challenges of MDUFMA to its staff and stakeholders. To ensure that the implementation of the new law proceeds smoothly, CDRH has worked with its stakeholders and is confident that the implementation of MDUFMA will result in significant benefits to industry, health care professionals, and, most importantly, patients.

Major Submissions Completed (Decision Cohort)

The table below summarizes the actions that ODE completed in fiscal years 1995-2005 (i.e., the "decision cohort"). Note that decisions may be made in one fiscal year for an application that was submitted in a previous fiscal year.

Table 2. Major Submissions Completed FY 95 - FY 05

TYPE OF SUBMISSION	1995 ODE& OIVD	1996 ODE& OIVD	1997 ODE& OIVD	1998 ODE& OIVD	1999 ODE& OIVD	2000 ODE& OIVD	2001 ODE& OIVD	2002 ODE& OIVD	2003 ODE& OIVD	2004 ODE Only	2005 ODE Only
Original PMAs	27	43	48	40	36	42	53	41	31	30	29
PMA Supplements	435	462	401	421	440	474	442	533	494	424	354
Original IDEs	210	260	272	325	305	320	284	307	246	217	238
IDE Amendments	213	218	220	225	268	251	207	251	217	162	208
IDE Supplements	3,181	3,121	3,777	4,209	4,224	4,335	4,803	4,711	4,424	4,336	4,226
510(k)s	7,948	5,563	5,155	5,229	4,593	4,397	4,150	4,376	4,132	3,376	3,184
Original HDE	0	0	2	4	6	6	4	6	2	6	2
HDE Supplements	0	0	0	0	3	10	11	13	24	22	31
Total	**12,014**	**9,667**	**9,875**	**10,453**	**9,876**	**9,835**	**9,954**	**10,238**	**9,570**	**8,573**	**8,272**

- Premarket Approval Applications (PMAs)

In FY 05, ODE completed 121 PMA actions. These actions included 43 filing decisions, 29 major deficiency decisions, and 49 approval/approvable/not approvable decisions.

Of the 49 decisions made in FY 05 on original PMAs, 29 were approval orders, 14 were approvable and 6 were not approvable. Of the 29 approvals, 4 were for expedited PMAs. See Part 1 (ADVANCES IN PATIENT CARE) for a complete list of PMA approvals.

In FY 05, ODE completed 527 PMA supplement actions. These actions included 14 panel track PMA supplement filing decisions, 4 major deficiency decisions, 73 not approvable decisions, 82 approvable decisions and 354 approval decisions in FY 05.

- Premarket Notifications (510(k)s)

ODE completed 3,185 510(k) actions in FY 05. These actions included 2,784 substantially equivalent decisions, 108 not substantially equivalent decisions, and 293 other decisions such as withdrawn or deleted.

During the fiscal year, 684 Special 510(k)s received final decisions (662 were found substantially equivalent, 2 were found not substantially equivalent, and the remaining 20 had other decisions).

One hundred thirty-two abbreviated 510(k)s received final decisions (118 substantially equivalent, 3 not substantially equivalent, and 11 other decisions).

ODE made final decisions on 248 “third party” 510(k)s in FY 05, a 7% increase from the 231 final decisions in FY 04.

- Investigational Device Exemptions (IDEs)

Of the original IDEs which were complete enough to support substantive review, the percentage of IDEs approved on the first review cycle was 59% in FY 05. This represents a decrease from the FY04 performance level of 74%, primarily attributed to the increasing complexity of submissions, and the increasing number of combination product submissions.

Like original IDEs, the percentage of IDE supplements reviewed within the 30-day statutory timeframe was 100% in FY 05.

In FY 05, decisions, as follows, were made on 208 amendments: 75 approvals (36%); 53 disapprovals (26%); and 80 other administrative actions (38%).

Automatic Evaluation of Class III Designation

The Food and Drug Administration Modernization Act of 1997 (FDAMA) amended Section 513(f) (21 U.S.C. 360c(f)) to provide a new mechanism to reclassify statutorily classified class III products. This provision, which is referred to as the Evaluation of Automatic Class III Designation provision (also known as "de novo" or "risk-based" classification), is intended to apply to low risk products that have been classified as class III because they were found not substantially equivalent (NSE) to any identifiable predicate device. The process permits the Secretary (FDA, by delegation) to reclassify certain low risk devices into class I or II on the basis of established risk-based classification criteria.

- Issued an order on August 4, 2005 classifying Endosensor with Delivery System and Endosensor Electronics System into class II 870.2855.
- Issued an order on January 14, 2005 classifying Decapinol Oral Rinse into class II 872.5580.
- Issued an order on November 4, 2004 classifying Hamilton Thorne Zona Infrared Laser Optical System (ZILOS-tk®) into class II 884.6200

515(b)

Section 515(b) of the Federal Food, Drug, and Cosmetic Act (the Act) specifies that FDA will promulgate regulations requiring that the class III devices specified below have an approval of an application for premarket approval (PMA). Class III devices are described in section 513(a)(1)(C) of the Act.

The devices covered by 515(b) requirements fall into two categories:

- Devices in commercial distribution before May 28, 1976 (preamendment devices) that were subsequently classified by the Food and Drug Administration (FDA) as class III devices by means of classification regulations promulgated under Section 513 of the Act.

- Devices offered for commercial distribution on or after May 28, 1976, (postamendment devices) that are determined through the 510(k) process to be substantially equivalent to class III preamendment devices.

Manufacturers of class III preamendment devices (categories 1 and 2 above) are allowed to commercially market their devices without an approved PMA until FDA publishes a final rule under 515(b) to require the filing of a PMA. In addition, these manufacturers are not required to submit a PMA until 30 months after the final promulgation of a final classification regulation or until 90 days after the publication of a final regulation requiring the submission of a PMA, whichever period is later (See 501(f)(2)(B)). FDA may allow more than 90 days after promulgation of a final rule for submission of a PMA.

ODE did not publish any proposed rules under this provision in FY 05,. ODE did publish one final rule:

- Published a final rule in the *Federal Register* on October 4, 2004 requiring Premarket Approval for Hip Joint Metal/Polymer or Ceramic/Polymer Semiconstrained Resurfacing Cemented Prosthesis.

Part 6 – Other Program Activities

Bioterrorism Preparedness

ODE continues to be involved in several critical 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.

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 October 2005 FDA CBER TSE Advisory Committee (TSEAC) meetings. At the October meeting, ODE presented the results from the September 27, 2005 meeting of the General Hospital and Personal Use Devices Advisory Panel meeting that discussed acceptable criteria for studies and claims related to TSEs. The ODE presentation also provided an update indicating there were no medical devices that have been cleared or approved with claims to reduce or remove TSE infectivity on surgical instruments. ODE and other CDRH offices have continued to be active in the intra-agency working group dealing with Chronic Wasting Disease (CWD) Decontamination.

Advisory Panel Activities

The Center's Medical Devices Advisory Committee (MDAC) consists of 18 panels, 13 in ODE and 5 in OIVD, that provide clinical and scientific advice to FDA in a wide range of medical specialties that are fundamental to the regulation of medical devices. The primary work of these panels involves: (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 and effectiveness of medical devices.

In FY 05, 16 ODE panel meetings were held. These panels reviewed and made recommendations on 9 PMAs, 1 HDE, 2 510(k)'s, 7 preamendment device classifications, 1 OTC designation and 5 general issues. The ODE panels reviewed PMAs for significant device breakthrough technologies such as a thoracic endoprosthesis for endovascular repair of the descending thoracic aorta, a mesh wrap implant for restraining cardiac

dilatation, a resurfacing hip system, a fetal monitor that uses ST waveform analysis, as well as silicone gel breast implants.

In FY 05, CDRH submitted approximately 53 homework assignments to Committee Management for clearance of Special Government Employees to provide outside expertise regarding various issues. Twenty Voting Members and 60 Consultants were cleared for these assignments. One waiver was required. The Center sought input from Advisory Panel members on the following types of documents: PMAs, PMA Supplements, PMA Amendments, 510(k)s, pre-IDEs, IDEs, HDEs, Postmarket Initiative (MDRs and PMAs), Guidance documents and general scientific discussions.

In FY 05, there were 15 training sessions for new ODE panel members and consultants. At 8 of the ODE meetings there were briefings on the new postmarket study design and follow-up procedures introduced on January 1, 2005, and at 7 ODE meetings there was a presentation about FDA's Critical Path Initiative.

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 and employment as well as research grants and contracts to identify any potential or imputed conflicts of interest. Individuals interested in becoming panel members should send their curriculum vitae to Geretta.Wood@fda.hhs.gov.

The MDAC panels ensure that the agency has access to the nation's outstanding medical and scientific experts and make the FDA medical device review process transparent to all stakeholders. CDRH greatly appreciates the many contributions that the advisory panel members and consultants make to the challenging tasks of the medical device review process.

The following 10 ODE panels of the Medical Devices Advisory Committee met during FY 05:

Anesthesiology and Respiratory Therapy
Circulatory System
Dental Products*
Ear, Nose and Throat*
Gastroenterology and Urology
General and Plastic Surgery
General Hospital and Personal Use
Neurological
Obstetrics and Gynecology
Orthopaedic and Rehabilitation

*Joint panel meeting

Transcripts from the Medical Devices Advisory Committee meetings can be found at: http://www.fda.gov/ohrms/dockets/ac/acmenu.htm

ODE Application Integrity Program

Under the Application Integrity Program (AIP), ODE has considered many cases concerning the integrity of data submitted to the agency in premarket applications. During FY 05, we placed one application on Integrity Hold and removed the Integrity Hold on two applications.

Part 7 - Program Support

Freedom of Information Requests

ODE staff received 706 FOI requests during FY 05, a decrease from 972 in the last fiscal year. During FY 05, the number of FOI requests closed was 637 compared to 547 in FY 04. The total number of FOI requests pending in ODE at the end of FY 05 is 422 compared to 587 in FY 04.

Congressional Inquiries

Staff from ODE responded to Congressional inquiries and participated in briefings on the following topics – breast implants, electromagnetic treatment devices, spinal cord injuries, cervical discs, total joint prostheses, multiple artificial disc, hemostatic devices, automatic external defibrillators, carotid artery stenosis, and pacemakers. ODE also participated in hearings of Congressional committees and briefings of Congressional staff during FY 05. These dealt primarily with FDA's budget and MDUFMA.

Publications

During FY 05, ODE staff authored 34 manuscripts for publication in professional and scientific journals and delivered 138 presentations at professional, scientific and trade association meetings. See Appendix B for a bibliography of publications.

ODE Vendor Day

ODE coordinated the Dental Implants Vendor Day which was held on June 16, 2005. The Vendor Day is an educational interaction between device manufacturers and ODE employees that highlights the scientific basis for a product line with the goal that this interaction will benefit both the manufacturers and attendees. Representatives from 3implant, Zimmer, Sterngold, and Dentsply participated. There were over 100 attendees.

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. Twenty-six employees completed the formal program.

Recruitment

To enhance the Center's effort to increase the hiring of minorities and those with a disability, ODE participated in the 2005 Marriott Bridges Students with a Disabilities Program. In addition, ODE participated in the 2005 DHHGNTC Minority Career Fair, and we partnered with the Agency's EEO/Diversity Management Office to support the Hispanic Employment Forum, the National Medical Association Career Fair, the Association of American Indian Physicians Conference, and the Society for Advancement of Chicanos & Native Americans in Science Conference and Career Fair.

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 2005 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. Several Office and Center employees participate in this on-going program.

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.

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 05, ODE held 4 video conferences with industry and Federal agencies.

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.

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 1-800-638-2041 or 240-276-3103 directly between the hours of 8:00 a.m. – 5:00 p.m. EST
Fax: 240-276-3101

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. In order to submit an HDE application for a medical device, the medical device must first meet the definition of a Humanitarian Use device (HUD) under 21 CFR 814.3(n). A HUD is a "medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year." 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 and the sponsor to track each IDE from the time it is originally submitted until the time it is approved.

IDE Supplements

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

Premarket Notifications (510(k))

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

Appendix B – ODE Publications

The following is a bibliography of articles and abstracts prepared by the ODE staff and published or presented during FY 2005.

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Staff College Presenters and Faculty

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Brown, Sheila
Ciarkowski, Art
Chakrabarti, Kish
Cotterell, Alison
Gatling, Robert
Good, John
Hawthorn, Anne
Ho, Charles
Horbowyj, Roxolana
Jensen, D. Nick
Kammula, Raju
Less, Joanne
Lewis, Brian
Mallis, Elias
Mann, Eric
Morris, Janine
Neuland, Carolyn
Nguyen, Thinh
Pena, Carlos
Pluhowski, Nancy
Provost, Miriam
Rechen, Eric
Rosecrans, Heather
Sacks, William
Wolanski, Nicole
Zimmerman, Barbara

ODE Standards Liaison Representatives

Abel, Dorothy
Adjodha, Michael
Allen, Peter
Allen, Samie
Anderson, Jodi
Baker, Karen
Beers, Everette
Berman, Michael
Berman, Sheryl
Bezabeh, Shewit
Blackwell, Angela
Bowley, Sue
Brown, Daniel
Burdick, William
Byrd, Laura
Calogero, Don
Carey, Carole
Cavanaugh, Ken
Chen, Tzeng
Cheng, Jim
Ciarkowski, Art
Colburn, Scott
Cornelius, Mary Jo
Cunningham, Terrell
Cygnarowicz, Teresa
Daws-Kopp, Kathryn
DeLuca, Robert
Demian, Hany
Doyle, Bob
Drum, Bruce
Eydelman, Malvina
Felton, Richard
Ferriter, Ann
Fox, Pat
Foy, Jonette
Gantt, Doyle

Gonzalez, Gema
Goode, Jennifer
Goode, John
Gouge, Susan
Graham, Ann
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
Lipman, Jason
Lochner, Donna
Maloney, William
Malshat, Vasant
Marshall, Felicidad
Mattamal, George
Mayhall, Elaine
McCarthy, Denis
McCool, Barbara
Melkerson, Mark
Mills, Kristin
Mulry, Kevin
Naveau, Irene
Nell, Diane
Nimmagadda, Venkat
Nutter, Cathy
Ogden, Neil
O'Lone, Martha
Patel, Neel
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
Tillman, Donna-Bea
Toy, Jeffrey
Turtil, Steve
Warburton, Karen
Weitershausen, Joanna
Wentz, Catherine
Whipple, David
Witten, Celia
Wood, Geretta
Yen, Dwight
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	http://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 10/01/06

OFFICE OF THE DIRECTOR

Director: Donna-Bea Tillman, Ph.D.
Deputy Director Clinical: Aron Yustein, M.D.
Deputy Director Engineering & Science Review: Miriam Provost, Ph.D.
Integrity Officer: Carl DeMarco, J.D.
Advisory Panel Coordinator: Geretta Wood

PROGRAM OPERATIONS STAFF (POS)

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

PROGRAM MANAGEMENT OFFICE (PMO)

Director: Kathryn Appler
Deputy Director: Lesa Dowtin

DIVISION OF CARDIOVASCULAR DEVICES (DCD)

Director: Bram Zuckerman, M.D.
Deputy Director I: Donna Lochner
Deputy Director II: Barbara Zimmerman
Associate Director, Guidance & Policy: Arthur Ciarkowski
Clinical Trials Coordinator: Wolf Sapirstein, M.D.
Pacing, Defibrillator, And Leads Branch: Mitchell Shein*
Cardiac Electrophysiology And Monitoring Devices Branch: Elias Mallis
Interventional Cardiology Devices Branch: Ashley Boam
Circulatory Support & Prosthetic Devices Branch: Joshua Nipper*
Peripheral Vascular Devices Branch: David Buckles, Ph.D.

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

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

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

Director: Malvina Eydelman, M.D.
Deputy Director: Everette Beers, Ph.D.
Vitreoretinal & Extraocular Devices Branch: James Saviola, O.D.
Diagnostic & Surgical Devices Branch: Everette Beers, Ph.D.*
Intraocular & Corneal Implants Branch: Kesia Alexander, Ph.D.
Ear, Nose, & Throat Devices Branch: Eric A. Mann, M.D., Ph.D.

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

Director: Mark Melkerson
Deputy Director I: Barbara Buch, M.D.
Deputy Director II: Peter Rumm, M.D.
Plastic & Reconstructive Surgery Devices Branch: Stephen Rhodes
General Surgery Devices Branch: Neil Ogden
Orthopedic Joint Devices Branch: Jonette Foy, Ph.D.
Orthopedic Spine Devices Branch: Theodore Stevens
Restorative Devices Branch: Eric Chen*

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

Director: Chiu Lin, Ph.D.
Deputy Director: Ginette Michaud, M.D.
Anesthesiology & Respiratory Devices Branch: Ann Graham
General Hospital Devices Branch: Anthony Watson
Infection Control Devices Branch: Sheila Murphey, M.D.
Dental Devices Branch: M. Susan Runner, D.D.S.

*Acting

Appendix E – ODE Staff Roster

Office of the Director

Boler-Bonny, Adrien*
DeMarco, Carl
Doyle, Robert
Gornick, MaryAnn
Hobbs, Cathy
Phillips, Philip
Provost, Miriam
Pluhowski, Nancy
Tillman, Donna-Bea
Williams, Nailah
Yustein, Ron

Program Management Office

Appler, Kathryn
Colleli, Karen
Dowtin, Lesa
Jaeger, Jeff
Phillips, Shirley
Wedlock, Chuck

Program Operations Staff

Berk, Gene
Beverly, Pat
Brown, Sheila
Byrd, Laura
Demian-Rumer, Cindy
Fisher, Lisa
Garcia, Diane
Gatling, Robert
Harvey, Elisa
Hawthorn, Anne
Less, Joanne
Lyons-Drager, Linda
Melvin, Marsha
Nguyen, Thinh
Rechen, Eric
Romanell, Lawrence
Rosecrans, Heather
Sawyer-Major, Wanda
Simenauer, Paula
Shulman, Marjorie
Stuart, Julie (Brandi)
Wolanski, Nicole

Division of Cardiovascular Devices

Abel, Dorothy
Agler, Heather
Aguel, Felipe+
Almond, Chris
Anderson, Evan∴
Anderson, Nels
Berman, Michael
Boam, Ashley
Bowley, Susan
Brown, Michele
Buckles, David
Buckley, Donna
Carey, Carole**
Cavanaugh, Kenneth
Chandeysson, Paul
Chen, Eric
Cheng, Jim
Ciarkowski, Art
Correa, Gina∴
Enyinna, Kachi
Ewing, Lesley**
Farb, Andrew
Faris, Owen
Fleischer, Dina
Foy, Joni
Foy, Keith
Gantt, Doyle
Goode, Jennifer
Hampshire, Victoria
Heaton, Henry (Tom)**
Higginson, Kathy++
Hillebrenner, Elizabeth
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
Leville, Lisa
Lewis, Brian
Lochner, Donna
Mallis, Elias
Maskara, Barun
Mezu-Nwaba, Nina
Moynahan, Megan
Muni, Neal∴
Nell, Diane
Nicholas, Gary∴
O'Callahan, Kathyrn∴
Pena, Ileana∴
Peters, Kimberly
Pinto, Hina
Rabaglia, Jennifer∴
Ramdat, Deb
Reilly, Sabina
Richards, Robert[++]
Riemenschneider, Bill
Ryan, Tara
Samadnejad, Sami
Sapirstein, Wolf
Shein, Mitchell
Shoemaker, Linda
Smallwood, Senora
Smith, Angela
Stiegman, Glenn
Swain, Julie∴
Swink, James∴
Terry, Doris
Tovar-Calderon, Oscar[+]
Ulmer, Kwame
Usher, Wil
Vaughan, Carolyn
Vo, Tamanh
Weintraub, Ron∴
Wentz, Catherine
Wood, Geretta
Yuan, Jay
Zimmerman, Barbara
Zuckerman, Bram

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

Adjodha, Michael
Betz, Robert
Bezabeh, Shewit
Blackwell, Angela
Blount, Sharon
Brooks, Mary
Browne, Myra
Burdick, William
Chapman, Richard
Chisley, India
Colburn, Scott
Cotterell, Alison∴
Cunningham, Terrell
Floyd, Chirelle
Fox, Pat
Gantt, Gail
Goldman, Julian∴
Graham, Ann
Guay, Justin
Harkavy, Lorraine
Husband, Michael
Jayan, Geetha
Jordan, Erika
Johnson, Tametria
Lapman, Caityln•
Leveille, Lisa
Lin, Chiu
Lippman, Jason
Maloney, William

Mayhall, Elaine
Michaud, Ginette
Mulry, Kevin
Murphey, Sheila
Norfleet, William∴
O'Connell, Linh
O'Lone, Martha
Patel, Neel
Pierce, Eric∴
Riley, Erin
Rios, Michelle
Rizk, Sarah∴
Robison, Mary Jo
Roy, Joydeb
Runner, Susan
Ryan, Michael
Samuels-Reid, Joy
Sauberman, Harry
Schmidt, Jennifer
Steen, Andrew∴
Soprey, Pandu
Teresinski, Doris
Turtil, Steve
Watson, Anthony
Weininger, Sandy#

Division of General, Restorative, and Neurological Devices

Allen, Peter
Allen, Samie
Anderson, Jodi
Arepalli, Sambasiva
Ashar, Binita
Basu, Sankar
Berkowitz, David
Berne, Bernard
Bowsher, Kristen
Brown, Sheila
Buch, Barbara
Chen, Long
Costello, Ann
Courtney, Michael
Cox, Ann#
Dawisha, Sahar
De Del Castillo, Sergio
DeLuca, Robert
Demian, Hany
Doll, Sara∴
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
Hinckley, Steve
Holden, John
Horbowyj, Roxi
Hudson, Peter
Janda, Michel
Jean, Ronald
Kaiser, Aric
Krause, David
Lazar, Ronald∴
Lee, Kyung
Lerner, Herbert
Marjenin, Timothy++
Mattamal, George
Melkerson, Mark
Mills, Kristin
Mishra, Nirmal
Ogden, Neil
Peck, Jonathan
Pena, Carlos
Phillips, Mary Ellen
Rhodes, Hollace
Rhodes, Stephen
Rossi, Jeffrey
Schlosser, Michael∴
Schroeder, Marie
Scudiero, Janet

Shure, Deborah∴
Sloan, Nadine
Stevens, Theodore
Stiegman, Glenn
Sturniolo, Michael
Sung, Pei
Uchida, Taka∴
Vega, Dora
Warfield, Diane
Weiblinger, Richard
Witten, Celia
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+
Buttemere, Clay
Callaway, Jan
Calogero, Don
Chen, Tzeng
Cohen, Ethan#
Cohen, Linda
Cunningham, Bradley
Cygnarowicz, Teresa
Drum, Bruce
Eydelman, Malvina
Falls, Deborah
Gola, Shikha∴
Gouge, Susan
Hilmantel, Gene
Hutter, Joseph
Jones, Susanna
Kane, James
Kaufman, Daryl
Kiang, Tina
Lepri, Bernard
Leslie, Sharmeka
Malshet, Vasant
Mann, Eric
McCarthy, Denis
McGhee, Eleanor
Moore, Shirley
Nandkumar, Srinivas
Nicholas, Marsha
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

Allen, Cheryl
Bailey, Michael
Baxley, John
Bechtold, Stephanie∴
Bilek, Stacie
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
Eba, Felisa

Gonzalez, Gema
Garma, Pharoah∴
Hayes, Wendelin
Heaton, Thomas*
Herrera, Hector
Holmes, Myia*
Howell, Kimberly
Isayeva, Irada#
Jevtich, Milorad
Kammula, Raju
Kang, Andy
Kuchinski, Michael
Lauritsen, Kristina
Mackey, Cheryl
McCool, Barbara
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-Zacharek, Claudia∴
Sacks, William*
Segerson, Dave
Seiler, Jim
Shoback, Barbara##
Shuping, Ralph
Smirniotopoulos, James
Stephenson, Rebecca
Stratton, Slade∴
Straughn, Kellie
Tai, Mary Ann∴
Virmani, Mridulika
Vorvolakos, Katherine**
Wallner, Paul∴
Wersto, Nancy
Whang, Joyce
Williams, Richard
Zaremba, Loren

* Contractor
** ORISE Contractor
# Joint Appointment w/OSEL
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+ MDUFMA Joint Hire w/OSB
++ Co-Op Employee
♦ Shared Services
• Summer Student
∴ MDFP Hire