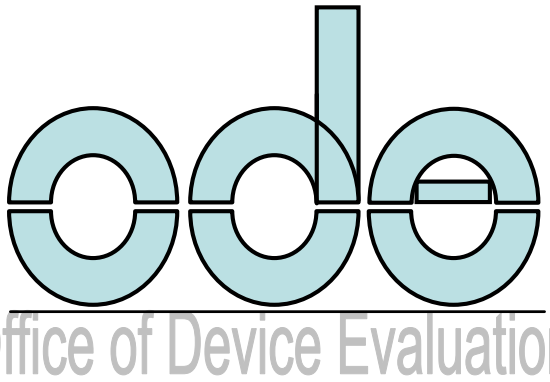
OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 2006 and

FISCAL YEAR 2007



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

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PREFACE

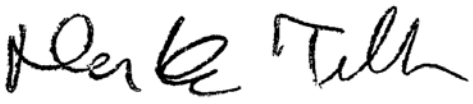
Dear Reader:

When we review our accomplishments, major challenges, and goals for 2006 and 2007, we are proud of what we have accomplished with our collective endeavors.

The passage of the Food and Drug Administration Revitalization Act of 2007 (FDARA) reauthorized FDA to collect user fees and contained other provisions for the medical device review program. FDARA also presents us with a more challenging set of performance goals. In order to meet these new challenging goals we have done several things. We developed an interactive review guidance document; modified our Center Tracking System (CTS) to enable staff to manage the new performance goals and the interactive review process; we are revising the original MDUFMA I PMA and 510(k) guidance documents to reflect the changes in the MDUFMA II legislation; we established new review timelines for original PMAs, PMA supplements, and 510(k)s to reflect the changes in the MDUFMA II legislation; and we have been developing essential training for all staff members on the new MDUFMA II performance goals, the interactive review process, and the new CTS features.

MDUFMA performance goals, Post-market Transformation, and rapidly advancing medical device technology present new challenges that necessitate further changes to the ODE program. I have the utmost confidence in our ODE staff for their continued support and commitment to promote and protect the public health. With all of us working together, we will be successful in meeting these challenges.

In closing, I want to acknowledge the support from our Center Director and the support from the other Offices within CDRH. Collaboration and communication are essential to the CDRH mission to promote and protect public health.



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

Part 1 – Advances in Patient Care

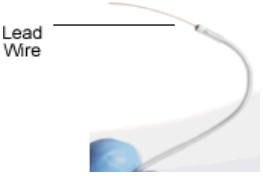
In Fiscal Years 2006 and 2007, the Office of Device Evaluation (ODE) approved and cleared thousands of devices used to diagnose and treat a wide variety of medical conditions. Below we highlight several new medical devices and devices with new indications approved or cleared during the 2006 and 2007 fiscal years that we believe will have a particular impact on patient care.

FY 06 SECTION

Heart Devices

The AbioCor® Implantable Replacement Heart, H040006, by Abiomed, Inc. was approved as a new humanitarian device exemption on September 5, 2006. The AbioCor® is an artificial replacement heart consisting of right and left blood pumps implanted in the chest. The pumps are connected to the patient's own remaining heart tissues (called the atria) and blood vessels, since the patient's own ventricles have been removed. This device may provide heart function to patients with severe heart failure. In addition, the device may have the ability to restore normal circulation as well as kidney and liver function. The AbioCor® is indicated for use in severe biventricular end stage heart disease patients who are less than 75 years old, are not cardiac transplant candidates, require multiple inotropic support, are not treatable by LVAD destination therapy, and are not weanable from biventricular support if on such support. More information can be found at http://www.fda.gov/cdrh/ode/h040006sum.html.

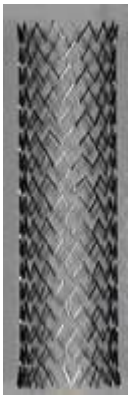
The STAN® S31 Fetal Heart Monitor, P020001, by Neoventa Medical AB was approved on November 1, 2005. The device is a new type of fetal monitor that uses the fetal electrocardiogram (ECG) obtained through a fetal scalp electrode during labor to help the doctor or midwife decide whether to allow the mother to continue to labor or to intervene and deliver the baby. More information can be found at http://www.fda.gov/cdrh/pdf2/P020001.html.



The Tupos LV/ATx and Kronos LV-T CRT-Ds and Corox OTW Steroid Lead, P050023, by Biotronik Inc. was approved on August 10, 2006. The Tupos LV/ATx and Kronos LV-T Cardiac Resynchronization Therapy Defibrillator (CRT-D) Systems are

implantable cardioverter defibrillators (ICDs) that also provide Cardiac Resynchronization Therapy (CRT) for patients with heart failure who need an ICD. The CRT-D is surgically implanted below the collarbone, just beneath the skin. One lead is placed in an upper heart chamber (the right atrium), a second lead is placed in the right lower heart chamber (ventricle), and a third lead is placed in a vein that overlies the left lower heart chamber. When the CRT-D senses dangerous abnormal heart rhythms (arrhythmias), it shocks the heart into a normal rhythm. The CRT coordinates the beating of the left and right ventricles so they work together to more effectively pump blood throughout the body. The Kronos LV-T CRT-D also has BIOTRONIK's Home Monitoring technology that allows a physician to remotely monitor performance of a patient's implanted system and condition via the Internet. The CRT-D Systems are for use in patients who have heart failure and are at risk of sudden cardiac death. They are indicated for use in patients who have abnormally fast heart arrhythmias (indicated for an ICD); exhibit symptoms related to heart failure; and receive optimized and stable Congestive Heart Failure (CHF) medicines. The Tupos LV/ATx is also indicated for patients who, in addition to an indication for a CRT-D device, have atrial tachyarrhythmias or are at risk of developing atrial tachyarrhythmias.

The Corox OTW Steroid leads are intended for implantation via the coronary veins to provide long term cardiac pacing when used in conjunction with a compatible pulse generator. More information can be found at http://www.fda.gov/cdrh/pdf5/P050023.html.



The Cordis PRECISE™ OTW Nitinol Stent System, P030047, by the Cordis Corporation, was approved on September 22, 2006. The device consists of a stent and delivery catheter system (PRECISE™ OTW Nitinol Stent System) and is used in conjunction with an embolic protection system (ANGIOGUARD™). The stent is a metal mesh tube on a delivery catheter, and the embolic protection device is a micromesh filter basket on the end of a delivery catheter. The ANGIOGUARD™ wire is inserted into the vessel in the groin and moved up to the blood vessel in the neck a little past the blockage. The end of the ANGIOGUARD™ opens like an umbrella. It has small holes to allow blood to flow through, but small enough to catch any pieces of debris that may break off from the blockage. After the ANGIOGUARD is opened, the physician uses the same wire to move the PRECISE stent to the blocked area. The PRECISE stent is then allowed to come out of the catheter and opens automatically over the blockage. The catheter is removed, and another catheter is put up into the neck vessel to close the ANGIOGUARD and removed, along with any pieces of debris that were trapped.

The PRECISE stent system is used in patients who have had a stroke, or who have a very tight (≥80%) blockage in the vessels of the neck. The stent is supposed to open

blockages in the blood vessel in order to prevent future strokes. Stents should not be used in patients who cannot take blood thinners or who have bleeding disorders, who are allergic to nitinol, who have blockages at the beginning of the neck artery, or who have problems preventing the catheter from getting to the blockage. More information can be found at http://www.fda.gov/cdrh/pdf3/P030047.html

Septal Occluders

The GORE HELEX™ Septal Occluder, P050006, by W.L. Gore & Associates was approved on August 11, 2006. The HELEX Septal Occluder is a minimally invasive device intended for the closure of an Atrial Septal Defects (ASDs) using cardiac catheterization. The device is made up of two parts, the delivery system and the occluder. The delivery system is a hollow catheter used to move the occluder through blood vessels to the defect in the atrial septum. The occluder is a permanent implant consisting of a circular wire frame covered with a thin GORE-TEX membrane. The wire frame is made of a nickel-titanium alloy called nitinol. More information can be found at http://www.fda.gov/cdrh/pdf5/P050006.html.

Bone Void Fillers, Dental

The GEM 21S (Growth Factor Enhanced Matrix), P040013, from Biomimetics Therapeutics Incorporated was approved on November 18, 2005. It is a combination of synthetic beta tricalcium phosphate particles and rhPDGF-BB, a highly purified recombinant human plate-derived growth factor. GEM 21S is indicated to treat the following periodontal related defects:

- Intrabony periodontal defects;
- Furcation periodontal defects; and,
- Gingival recession associated with periodontal defects.

This product is the first bone filling material approved which contains a therapeutic biologic. More information can be found at http://www.fda.gov/cdrh/pdf4/P040013.html.

Adhesion Prevention

The Adept® Adhesion Reduction Solution (4% Icodextrin), P050011, by Innovata plc was approved on July 28, 2006. This device is a pale yellow fluid that contains icodextrin. The fluid is supplied sterile, in a single-use bag. The Adept® Adhesion

Reduction Solution is used in patients undergoing laparoscopic gynecological surgery (surgery on the female reproductive organs, e.g., ovaries, uterus, fallopian tubes) to reduce the number or severity of adhesions (scar tissue that binds together normally separate tissues) in the abdomen. The fluid is used during surgery and/or placed in the abdomen at the end of the surgery, to separate and protect tissues, decreasing the number of new adhesions after surgery. More information can be found at http://www.fda.gov/cdrh/pdf5/P050011.html.

Hip Prostheses

The Birmingham Hip Resurfacing (BHR) System, P040033, by Smith & Nephew Orthopaedics was approved on May 9, 2006 as a new expedited, first-of-a-kind premarket approval. The Birmingham Hip Resurfacing (BHR) System is a metal on metal resurfacing artificial hip replacement system, surgically implanted to replace a hip joint. The BHR is called a resurfacing prosthesis because only the surface of the femoral head (ball) is removed to implant the femoral head resurfacing component. The BHR system is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision. More information can be found at http://www.fda.gov/cdrh/pdf4/P040033.html.

Cervical Cancer

Color map generated by the LUMA™ System to help a doctor decide where to biopsy cervical tissue

The LUMA™ Cervical Imaging System, P040028, by MediSpectra, Inc. was approved on March 16, 2006 as a new expedited approval. The LUMA™ Cervical Imaging System is an optical detection system that helps the doctor identify areas on the cervix that may have disease (i.e., areas that are likely to contain cancer or precancerous cells). The doctor uses the device immediately after colposcopy to decide where to take additional biopsies. The LUMA™ will help improve the chances that the doctor does not miss an area that may contain cancer or precancerous cells. More information can be found at http://www.fda.gov/cdrh/pdf4/P040028.html.

Spinal Implants

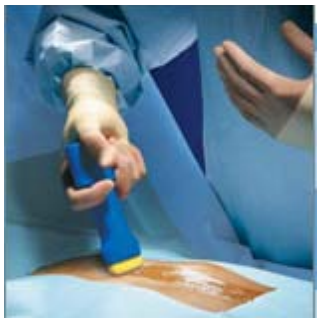
The X STOP® Interspinous Process Decompression System, P040001, by St. Francis Medical Technologies, Inc. was approved on November 21, 2005. The X STOP® implant is used to relieve symptoms of lumbar spinal stenosis, a narrowing of the passages of the spinal cord and nerves. The device is a titanium implant that fits between the spinous processes of the lower (lumbar) spine. It is made of titanium alloy and consists of two components: a space assembly and a wing assembly. More information can be found at http://www.fda.gov/cdrh/pdf4/P040001.html.

Loss of Smell

The HealthCheck™ Home Test for Loss of Smell, K051653, was cleared on March 27, 2006, via the De Novo process. The device is manufactured by MFG Inovations, Inc.

The HealthCheck™ Home Test for Loss of the Sense of Smell is packaged in a small carton which contains (1) an Instruction Book, (2) a booklet containing twelve microencapsulated smell strips, each on a separate page, with instructions for scoring the test and an Answer Key, and (3) a Physician Information Card. Each strip releases a common and easily identifiable odor when it is scratched. The user is asked to identify the odor associated with each strip by choosing an answer from one of four choices, only one of which is correct. The Answer Key at the end of the booklet indicates which odor was incorporated into each of the twelve smell strips. A user with a score of four or more incorrect answers is advised to consult with his/her physician. More information can be found at http://www.fda.gov/cdrh/pdf5/K051653.pdf.

Infection Control



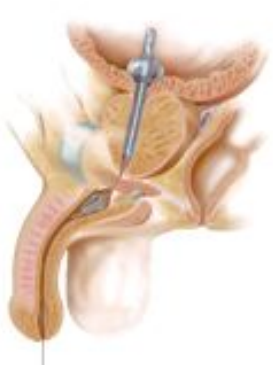
INTEGUSEAL Microbial Sealant, K052870, from Kimberly-Clark Corporation was cleared on September 29, 2006 as a surgical drape accessory. INTEGUSEAL Microbial Sealant is a film-forming cyanoacrylate-based product provided in a ready-to-use applicator. The Sealant is intended to be applied on the skin over commonly used surgical skin preparation products with standard surgical draping prior to a surgical incision. Upon polymerization,

INTEGUSEAL bonds to the skin, immobilizing the bacteria and thereby reducing the risk of skin flora contamination throughout a surgical procedure.

This product is one of only two products legally marketed in the USA that has been shown to reduce bacterial load from the skin during surgical procedures. More information can be found at http://www.fda.gov/cdrh/pdf5/K052870.pdf.

FY 07 SECTION

Urethral Stents



The Spanner™ Temporary Prostatic Stent, P060010, by AbbeyMoor Medical, Inc. was approved on December 14, 2006. This device is a sterile, disposable device, positioned in the prostatic urethra between the bladder neck and the external urinary sphincter. The Spanner™ is intended for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination in patients following minimally invasive treatment for benign prostatic hyperplasia (BPH) and after initial post-treatment catheterization. The stent portion of The Spanner™ prevents obstruction of the prostatic urethra and allows urine to drain from the bladder. More information can be found at http://www.fda.gov/cdrh/pdf6/P060010.html.

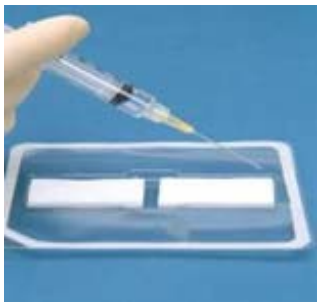
Excimer Laser

The VISX STAR S4 IR™ Excimer Laser System with Variable Spot Scanning (VSS™) and WaveScan WaveFront® System, P930016/S25, by AMO/VISX, Inc. was approved on July 11, 2007. LASIK, or laser in-situ keratomileusis, is a procedure in which the surgeon cuts a flap in the outer layers of the cornea, removes a small amount of the tissue beneath it with the laser, and then replaces the flap. CustomVue Monovision LASIK produces monovision correction in nearsighted (myopic) adults, with or without astigmatism, ages 40 years or older with normal age-related loss of ability to focus on near objects (presbyopia). This is accomplished by correcting all the nearsightedness in the patient's dominant eye (for seeing far away) and only part of the nearsightedness in the non-dominant eye (for seeing close up). CustomVue Monovision LASIK is a permanent operation to the cornea and those patients considering this procedure should first wear monovision contact lenses for at least a week to determine if they can

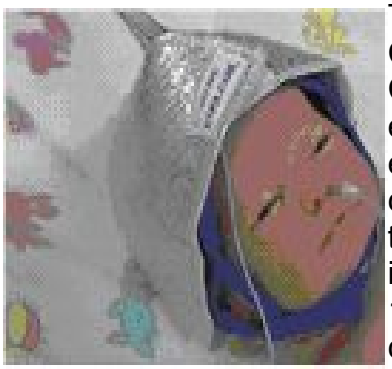
tolerate having one eye undercorrected. More information can be found at http://www.fda.gov/cdrh/pdf/P930016s025b.pdf.

Bone Graft

The INFUSE® Bone Graft, P050053, manufactured by Medtronic Sofamor Danek was approved on March 9, 2007. This device is a bone filling material for dental use consisting of two components, a bone protein, rHBMP2 and an absorbable collagen sponge. It is an alternative to grafting a patient's own bone. It is used to fill space where bone is needed in order to place endosseous dental implants. Endosseous dental implants are inserted in the jaw and have an exposed head that can be used to secure dental devices like a crown, fixed bridge, or dentures. INFUSE® Bone Graft is used in making enough bone in the sinus area to place endosseous dental implants in the upper jaw. It is also used to increase bone in extraction sites prior to implant placement. It can be used in situations where the patient's own bone is not sufficient to place implants. The device eliminates the need and difficulties of grafting bone from the patient's hip or other sites reducing the amount of pain and need for long recovery times. More information can be found at http://www.fda.gov/cdrh/mda/docs/p050053.html.



Infants



The Olympic Cool-Cap®, P040025, by Olympic Medical Corp., was approved on December 20, 2006. The Olympic Cool-Cap is indicated for use in full-term infants with clinical evidence of moderate to severe hypoxic-ischemic encephalopathy (HIE). Cool-Cap provides selective head cooling with mild systemic hypothermia to prevent or reduce the severity of neurologic injury associated with HIE. It is intended for use with infants with a birth weight of less than 1,800 grams, evidence of head trauma or skull fracture causing major intracranial bleeding or imperforate anus. More information can be found at http://www.fda.gov/cdrh/pdf4/P040025.html.

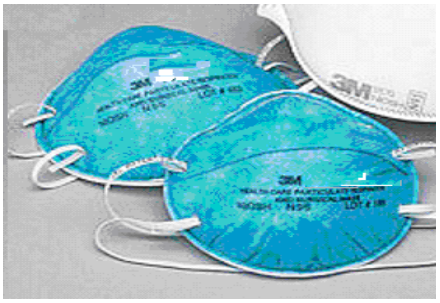
Washer/ Disinfector, Infection Control

The Manzi Mach 1 Cleaner Processor System, K060458, from Langford IC Systems, Incorporated was cleared on October 12, 2006. It is a single chamber automated bronchoscope washer disinfector indicated for use with the low foaming enzyme

chemical detergent MD10 and the High Level Disinfectant MS10 concentrate (MEC 0.49% PAA, minimum contact temperature of 120°F for a contact time of 15 minutes) for cleaning and high level disinfecting flexible bronchoscopes used in health care settings by health care workers. This product is the first automated washer disinfector system that uses a single chamber to automatically clean and high level disinfect bronchoscopes without the use of special connectors. More information can be found at http://www.fda.gov/cdrh/pdf6/K060458.pdf.

Respirator for General Use

In May 2007, CDRH approved the first N95 Respirators, K062070, for Use by the General Public in Public Health Medical Emergencies. These N95 respirators, manufactured by 3M Company were cleared via the De Novo Petition process. They are the first such devices that have been specifically evaluated and approved by FDA for use by the general public without the need for fit training and testing programs.



The FDA-approved 3M N95 Respirators for Use by the General Public in Public Health Medical Emergencies represent a significant advance in the degree of respiratory tract protection available to the general public for public health emergencies such as pandemic influenza. These respirators are required to have high filtration efficiency. They fit a wide variety of faces and provide a reasonable level of protection against aerosols of dangerous pathogens (germs), as demonstrated by testing in human subjects. Moreover, these respirators come with fit instructions so that they can be successfully used without special training or fit testing. They also have additional instructions, cautions and labeling that can help the wearer to reduce the risk of inhaling infectious airborne germs such as influenza virus. More information can be found at http://www.fda.gov/cdrh/pdf6/K062070.pdf.

Remote Medication Management System

The INRange Remote Medication Management System, K051338, manufactured by INRange Systems, Incorporated of Altoona, PA, was cleared by the FDA on June 13, 2007 via the De Novo Petition process. Information about the device can be found at http://www.fda.gov/cdrh/pdf5/k051338.pdf.

The INRange Remote Medication Management System is composed of clinical and communications software, a medication delivery unit, and medication packaging. The system is intended for use under the supervision of a licensed healthcare practitioner to

remotely deliver, manage, assess, alter dosing schedules, and/or monitor a patient's therapeutic medication regimens and adherence to those regimens in an outpatient setting. The INRange Remote Medication Management System:

- stores the patient's prescribed medications in a delivery unit
- allows a healthcare professional to remotely schedule the patient's prescribed medications
- notifies the patient when the prescribed medications are due to be taken
- releases the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and
- records a history of the event for the healthcare professional

The INRange Remote Medication Management System is used by healthcare professionals to aid in the control of the delivery of prescription drugs to patients in an outpatient setting. The medical device could help with outpatient adherence to complex medication regimens. There are no contraindications for this device.

Cervical Disc System

The PRESTIGE® Cervical Disc System, P060018, by Medtronic Sofamor Danek was approved on July 16, 2007. The PRESTIGE® is intended to replace a cervical disc (C3-C7) that was removed due to intractable radiculopathy and/or myelopathy (conditions that result from a disease or bulging disc). The PRESTIGE® is manufactured from stainless steel and includes superior (upper) and inferior (lower) parts that move with respect to one another by a ball and trough mechanism. The PRESTIGE® is attached to the vertebral body with stainless steel bone screws. The PRESTIGE® was the first approved cervical disc replacement and may maintain some motion at the implanted level as opposed to fusion. More information can be found at http://www.fda.gov/cdrh/pdf6/P060018.html.

Absorbable Suture

A 510(k) for Tepha, Inc.'s Tephaflex Absorbable Suture, K052225, was cleared on February 8, 2007 via the De Novo Petition process. Tephaflex Suture is the first medical device made from a polymer purified from genetically engineered bacteria. This De Novo device will set the pathway to allow other clearances or De Novo of other recombinant DNA technology products and devices. Premarket review included

evaluation of tests described in the Surgical Suture Special Controls Guidance and FDA Guidance on recombinant DNA technology products. In addition, data documenting chemical composition, biological purity, and pathogen inactivation were provided.

These studies showed that the TephaFLEX Absorbable Suture can be manufactured in a consistent and safe manner with chemical, biological and mechanical properties similar to other commercially distributed surgical sutures. The device is indicated for holding the edges of a wound together while the soft tissue heals. TephaFLEX Suture should not be used in cardiovascular, neurological or ophthalmic microsurgeries. The device should also not be used in patients allergic to the cells or the growth media used to produce the absorbable polymeric material. More information can be found at http://www.fda.gov/cdrh/pdf5/K052225.pdf.

Aneurysms

The Onyx® Liquid Embolic System (Onyx® HD-500), H060003, manufactured by ev3 Neurovascular, Inc. was approved on April 11, 2007. The device is an artificial material used to block blood flow into wide-neck aneurysms. The material is used to fill the aneurysm space, or pocket, and prevent the aneurysm from rupturing or increasing in size. Specifically, it is indicated for the treatment of intracranial, saccular, sidewall aneurysms that present with a wide neck (>= 4 mm) or with a dome-to-neck ratio < 2 that are not amenable to treatment with surgical clipping. These aneurysms present great difficulties for treatment since they can not be surgically corrected, nor do they have a shape that retains traditional embolic reagents, e.g., particulates, coils. The Onyx® material is injected through a catheter into the blood vessels of the brain at the location of the aneurysm. Upon contact with blood, the material solidifies so that the flow of blood into the aneurysm is blocked, and the material remains where it is placed. The device offers hope for patients with previously considered untreatable aneurysms. More information can be found at http://www.fda.gov/cdrh/ode/H060003sum.html.

Breast Implants

The MemoryGel Silicone Gel-Filled Breast Implants, P030053, by Mentor were approved on November 17, 2006. Each MemoryGel Silicone Gel-Filled Breast Implant consists of a single-lumen, round silicone elastomer shell, with a patch on the posterior side, which is filled with

MemoryGel, Mentor's proprietary silicone gel. The implants are available in a range of diameters, profiles (projections), and sizes, as well as in smooth and textured (Siltex) shell surfaces. The Mentor MemoryGel Silicone Gel-Filled Breast Implants are indicated for breast augmentation for women at least 22 years old, and for breast reconstruction for women of any age. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery. More information can be found at http://www.fda.gov/cdrh/pdf3/P030053.html.

The Inamed® Silicone-Filled Breast Implants, P020056, by Allergan were approved on November 17, 2006. Each Inamed® Silicone-Filled Breast Implant consists of a single-lumen, round silicone elastomer shell, with a patch on the posterior side, which is filled with silicone gel. The implants are available in a range of diameters, profiles (projections), and sizes, as well as in smooth and textured (BIOCELL®) shell surfaces. The Inamed® Silicone-Filled Breast Implants are indicated for breast augmentation for women at least 22 years old and for breast reconstruction for women of any age. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery. More information can be found at http://www.fda.gov/cdrh/pdf2/P020056.html.

Limb Salvage Shunt

A 510(k) for a vascular shunt device that will help save the arms and legs of soldiers injured in combat (K070323) was cleared on February 15, 2007. This device can be implanted on the battlefield to bypass damaged blood vessels and temporarily maintain blood flow to the injured limb. Prior to this clearance, there were no devices specifically available for treating injuries of this nature. When blood flow to the injured limb can be restored until the wounded soldier can be transported to a surgical facility, the likelihood of avoiding amputation and saving the injured limb improves significantly.

Temporary Limb Salvage Shunt (TLSS)

The vascular shunt device, known as a Temporary Limb Salvage Shunt (TLSS), is a tube formed from two layers of plastic. The TLSS has several features that optimize the

device for use in a trauma situation. These features include: (1) a self-sealing elastomer membrane that permits drugs to be injected directly into the shunt without loss of blood; (2) beveled ends that facilitate quick and effective placement of the device within the severed blood vessel; (3) graduated markings that provide visual confirmation of proper device placement; and (4) extra reinforcement in the center of the device so it can be cut to a shorter length if needed.

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 2006, ODE approved 27 PMAs and 2 HDEs; and in Fiscal Year 2007, ODE approved 27 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.

FY 06 Original PMA/HDE Approvals

		COMPANY	DEVICE
01-Nov-05	P020001	Neoventa Medical AB	STAN® S31 Fetal Heart Monitor
10-Nov-05	P040047	Bioform Medical, Inc.	Coaptite®
18-Nov-05	P040042	Irvine Biomedical, Inc.	Therapy™ Dual 8™ Cardiac Ablation System
18-Nov-05	P040013	Biomimetic Pharmaceuticals, Inc.	GEM 21S (Growth-factor Enhanced Matrix)
21-Nov-05	P040001	St. Francis Medical Technologies, Inc.	X STOP® Interspinous Process Decompression System
16-Dec-05	P050009	Biomet Manufacturing Corporation	C2a-Taper™ Acetabular System
20-Dec-05	P050021	QLT USA, Inc.	Ceralas I Laser System and Ceralink™ Slit Lamp Adapter
20-Dec-05	P040045	Johnson & Johnson/ Vision Care, Inc.	VISTAKON® (Senofilcon A) Contact Lenses
21-Dec-05	P050007	Abbott Vascular Devices (AVD)	StarClose™ Vascular Closure System
22-Dec-05	P030016	STAAR Surgical Company	Visian ICL™ (Implantable Collamer Lens)
16-Mar-06	P040028	MediSpectra, Inc.	LUMA™ Cervical Imaging System

		COMPANY	DEVICE
31-Mar-06	H040005	Karl Storz Endoscopy-America, Inc.	Karl Storz Semi-Rigid TTTS Fetoscopy Instrument Set, Karl Storz Rigid TTTS Fetoscopy Instrument Set with 0 or 12 degree scope, and Karl Storz Rigid TTTS Fetoscopy Instrument Set with 30 degree scope
04-Apr-06	P050026	QLT USA, Inc.	Quantel Activis Laser, Slit Lamp Adapters
9-May-06	P040033	Smith & Nephew Orthopaedics	Birmingham Hip Resurfacing (BHR) System
12-May-06	P040051	PaxMed Int'l	Stelkast Surpass™ Acetabular System
02-Jun-06	P050047	Inamed Corporation	Jucederm 24HV, 30 & 30HV
16-Jun-06	P050044	Orthovita, Inc.	Vitagel™ Surgical Hemostat
26-Jun-06	P050017	Cook, Inc.	Zilver® Vascular Stent
28-Jun-06	P040048	Zimmer, Inc.	Trilogy AB Acetabular System
10-Jul-06	P050014	Fujifilm Medical Systems USA, Inc.	Fuji Computed Radiography
28-Jul-06	P050011	Innovata PLC	Adept® Adhesion Reduction Solution
10-Aug-06	P050023	Biotronik, Inc.	Tupos LV/Atx CRT-D, Corox OTW
11-Aug-06	P060004	Carl Zeiss Meditec, Inc.	MEL 80™ Excimer Laser System
11-Aug-06	P050006	W.L. Gore & Associates, Inc.	GORE HELEX™ Septal Occluder
11-Aug-06	P040036	Biosense Webster, Inc.	NaviStar™ ThermoCool®
14-Aug-06	P050010	Synthes Spine Co., L.P.	PRODISC®-L Total Disc Replacement
05-Sep-06	H040006	Abiomed, Inc.	Abiocor® Implantable Replacement Heart
22-Sep-06	P030047	Cordis Corporation	Cordis PRECISE® Nitinol Stent System
26-Sep-06	P050038	Medafor, Inc.	Arista™ AH Absorbable Hemosat

FY 07 Original PMA/HDE Approvals

		COMPANY	DEVICE
27-Oct-06	P050025	Endotex Interventional Systems, Inc.	Endotex® Nextent® Carotid Stent
27-Oct-06	P020012	Artes Medical USA, Inc.	ArteFill
30-Oct-06	P040050	Uroplasty, Inc.	Macroplastique® Implants
16-Nov-06	P050031	Paragon Vision Sciences	Paragon Z CRT® Rigid Gas Permeable Contact Lenses

		COMPANY	DEVICE
17-Nov-06	P030053	Mentor Corporation	Mentor MemoryGel™ Silicone Gel-Filled Breast Implants
17-Nov-06	P020056	Allergan	Innamed® Silicone-Filled Breast Implants
14-Dec-06	P060010	AbbeyMoor Medical, Inc.	The Spanner™ Temporary Prostatic Stent
20-Dec-06	P040025	Olympic Medical Corp.	Olympic Cool-Cap®
20-Dec-06	P050033	Anika Therapeutics, Inc.	Cosmetic Tissue Augmentation Product
22-Dec-06	P050052	BioForm Medical, Inc.	Radiesse
22-Dec-06	P050037	BioForm Medical, Inc.	Radiesse
08-Jan-07	P050018	AngioScore, Inc.	AngioSculpt® Scoring Balloon Catheter
24-Jan-07	P060001	ev3, Inc.	Protégé® GPS™ and Protégé® RX Carotid Stent Systems
16-Feb-07	P050013	Kamm & Associates	Histoacryl® & Histoacryl® Blue Topical Skin Adhesive
09-Mar-07	P050053	Medtronic Sofamor Danek USA, Inc.	InFuse® Bone Graft
16-Mar-07	P060019	Irvine Biomedical, Inc.	Therapy™ Cool Path™ Ablation
11-Apr-07	H060003	ev3 Neurovascular, Inc.	Onyx® Liquid Embolic System
13-Apr-07	P050046	Guidant Corp.	ACUITY™ Steerable Lead
03-May-07	P060011	Rayner Surgical, Inc.	C-flex™ Model 570C IOL
08-May-07	P050004	Electro Medical Systems (EMS) S.A.	EMS Swiss Dolorclast®
08-May-07	H060001	Cordis Neurovascular, Inc.	Cordis Enterprise Vascular Reconstruction Device and Delivery System
03-Jul-07	P050016	Corin USA	Cormet Hip Resurfacing System
05-Jul-07	P050039	Exactech, Inc.	Novation™ Ceramic Articulation Hip System
16-Jul-07	P060018	Medtronic Sofamor Danek, Inc.	PRESTIGE® Cervical Disc System
23-Jul-07	P060002	Bard Peripheral Vascular, Inc.	FLAIR™ Endovascular Stent Graft
01-Aug-07	P050024	CryoCor, Inc.	CryoCor CryoAblation System
20-Aug-07	P050043	Morris Innovative Research, inc.	FISH™ (Femoral Introducer Sheath and Hemostatsis Device)
07-Sep-07	P040040	AGA Medical Corp.	Amplatzer® Muscular VSD Occl
28-Sep-07	P070009	Ethicon Endo-Surgery, Inc.	REALIZE™ Adjustable Gastric Band

FY 06 Expedited Original and Panel Track Supplement PMA Approvals

		COMPANY	DEVICE
21-Nov-05	P040001	Kyphon, Inc.	X Stop Interspinous Process Decompression System
22-Dec-05	P030016	Staar Surgical Co.	Visian ICL (Implantable Collamer Lens)
16-Mar-06	P040028	Medispectra, Inc.	Luma Cervical Imaging System
09-May-06	P040033	Smith & Nephew Orthopaedics	Birmingham Hip Resurfacing (BHR) System
22-Sep-06	P030047	Cordis Corp.	Cordis Precise Nitinol Stent System

FY 07 Expedited Original and Panel Track Supplement PMA Approvals

		COMPANY	DEVICE
20-Dec-06	P040025	Olympic Medical Corp	Olympic Cool-Cap
03-Jul-07	P050016	Corin U.S.A.	Cormet Hip Resurfacing System
16-Jul-07	P060018	Medtronic Sofamor Danek, Inc.	Prestige Cervical Disc System

De Novos Cleared In FY 06

K050939 – Cardiomems, Inc.
Cardiomems Endosensor with Delivery System – Cleared October 28, 2005

K051653 – Fmg Innovations, Inc.
Healthcheck™ Home Test for Loss of Sense of Smell - Cleared March 27, 2006

De Novos Cleared In FY 07

K060028 – Barnev, Ltd.
Computerized Labor Monitoring System – Cleared January 30, 2007

K052225 – Tepha, Inc.
Absorbable Poly-4 Hydroxydrobutyrate (P4HB) Surgical Suture – Cleared February 8, 2007

K062070 – 3M Company
3M N95 Home Respirator with Fluid Resistance; 3M N95 Home Respirator – Cleared May 8, 2007

K051338 – InRange Systems, Inc.
Remote Medication Management System – Cleared June 13, 2007

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@fda.hhs.gov
Phone: Toll Free 1-800-638-2041 or 240-276-3103 directly between the hours of 8:00 a.m. – 4:30 p.m. EST
Fax: 240-276-3101
Mail: Consumer Staff, CDRH/FDA, 1350 Piccard Drive, HFZ-210, Rockville, MD 20850

Part 2 – Reports from ODE Divisions

In the following sections, each of the ODE review Divisions reports on some of the combined 2006/2007 important accomplishments.

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

DAGID Staff Subject Matter Experts on Emergency Preparedness and Influenza

DAGID staff expertise about personal protective devices and seasonal and pandemic influenza has been sought for review of subject-matter documents from other agencies, such as, CDC and OSHA. In addition, DAGID staff represents CDRH on several Department, Agency-wide committees as well as CDRH committees. A sampling of the committees DAGID staff served on is below:

- CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC)
- FDA's Pandemic Influenza Preparedness Task Force participants
- DHHS Respiratory Protection Device Working Group
- FDA's Emergency Use Authorization Working Group on Masks and Respirators
- DHHS Pandemic and Seasonal Influenza Risk Management Committee

DAGID launches the "Reviewer Round Table" Series

In March 2006, DAGID launched an exciting new program called "Reviewer Round Table." The program is an opportunity to informally have a broad discussion about devices that are "simple or complicated, unique or challenging, or just one that presents its own unusual "issues." Bimonthly one of DAGID's branches, Anesthesiology and Respiratory Devices (ARDB) Branch, General Hospital Devices Branch (GHDB), Infection Control Devices Branch (INCB), or Dental Devices Branch (DEDB), is responsible for presenting an interesting case study about a device. The case study can focus on pre-market approval issues, post-market follow-up, or special or specific unique device qualities. The presentations have included discussions about the challenges related to device reviews, and decisions concerning approval or clearing of devices. By bringing these discussions to the staff of the entire Division the sharing of information is expanded beyond the immediate review team. This allows for added input, often leading to an enhancement of the considerations necessary for added value to the review process. It also minimizes the "silo" effect and encompasses a broader scope of ideas.

Interagency Working Group

The Infection Control Devices Branch (INCB) works closely with the Centers for Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA) through quarterly teleconferences. The purposes of the meetings are to keep all three agencies apprised of public health issues related specifically to disinfection and sterilization, disease outbreaks including avian influenza and possible pandemic influenza, other disease outbreaks, such as, norovirus gastroenteritis and *Clostridium difficile* infections throughout the community and in unrecognized risk groups, and other high profile and potentially dangerous public health problems. Some of the issues recently addressed include surgical N95 respirators and surgical masks.

Single Use Devices Post -Market Issues (PMI) Action Teams

Infection Control Review Staff participated in the Post-Market Issues (PMI) Action Team for Reprocessing of Single Use Devices (SUDs). The overall goal is to improve the accuracy of medical device adverse event reporting to the Agency, and to enhance the Agency's data gathering and collating abilities with regard to reprocessed SUDs. The efforts of the Action Team will allow for improvements in speed and accuracy of data recovery, and to enable better integration of premarket activities and post-market research. These efforts have already facilitated rapid responses to a Congressional inquiry. For a summary of recent activities in the field of Reprocessing of SUDs, see http://www.fda.gov/cdrh/reuse/.

Infusion Pump Working Group

An Infusion Pump Working Group (WG) has been established to develop a Center action plan to evaluate postmarket experience with infusion pumps to determine how to improve the premarket review process. Additional objectives are to establish better communication across the Center regarding infusion pump issues and to increase interoffice responsiveness to infusion pump recalls by incorporating more involvement from the technical experts within the Center at an early stage.

CDRH Artificial Pancreas Working Group

The CDRH Artificial Pancreas Working Group was established to create innovative review processes that will accelerate the accessibility of an artificial pancreas (i.e., a closed-loop glycemic control device). This effort is aligned with FDA's decision to add the Artificial Pancreas Project as one of its Critical Path Initiatives. The group,

consisting of representatives from ODE, OIVD, OSB, and OSEL, sets CDRH review policy for these devices. They also coordinate their efforts with the Interagency Artificial Pancreas Working Group which is working on more global issues. Through collaboration with stakeholders and while applying sound scientific principles, this working group strives to develop strategies that will advance the development of new technologies in this area.

Dental Branch Represents FDA as Liaison to the American Dental Association Council on Scientific Affairs

The Dental Branch represents FDA as a liaison to the Council on Scientific Affairs of the American Dental Association (ADA). The Council, which includes both American and Canadian association representatives and liaisons from the National Institutes for Health, the Centers for Disease Control and Prevention, the American Association of Dental Research, and other associations, meets at the headquarters of the American Dental Association. The Council is composed of leading dental academicians, researchers, and association leaders from across the U.S. As a liaison, the Dental Branch presents updates on FDA dental activities, such as new guidance documents, and addresses questions from the Council on FDA scientific issues, regulations, the approval process, clinical trial design, policies regarding products regulated by FDA, and issues of interest to the Scientific Council.

DIVISION OF CARDIOVASCULAR DEVICES (DCD)

Coronary Drug-Eluting Stent Safety Evaluation Initiative

The Division of Cardiovascular Devices, in conjunction with the Office of Surveillance and Biometrics, developed a program to keep the public apprised of adverse event risks resulting from the implantation of coronary drug-eluting stents (DES). DES are implanted to improve heart blood flow through diseased coronary arteries. This initiative was prompted by reports of a small but significant increase in the risk of late stent thrombosis (stent clotting) compared to bare metal stents, recognized 1 year after DES placement. In response to this signal, in September 2006, FDA published a statement on the FDA web site informing the public of this information. The statement also announced that a meeting of the FDA Circulatory System Devices Advisory Panel would be held to assess the risk of stent thrombosis and determine if additional actions are warranted. This advisory panel meeting was held on December 7 – 8, 2006, and it served as a public forum for the presentation and discussion of clinical data relevant to the DES thrombosis issue for patients treated both according to the approved DES indications and those treated “off-label,” or outside the approved indications. The advisory panel concluded that, when used according to their approved indications, both FDA-approved DES are associated with a small increase in late stent thrombosis events, but that these risks do not outweigh the benefits of DES as compared to bare

metal (uncoated) stents. The panel also concluded that off-label use increased the risk of adverse events, and that additional clinical data are needed to fully evaluate these risks. The panel also recommended larger clinical studies to evaluate DES thrombosis risks in all patients. Finally, the panel recommended that labeling for DES be updated to reflect current ACC/AHA/SCAI guidelines which recommend extension of the duration of dual anti-platelet therapy (aspirin plus clopidogrel) to 12 months in DES-treated patients who are at low risk for bleeding complications. This information was further communicated to the public in a January 2007 statement on the FDA web site. DCD and OSB continue to work together to monitor DES safety and inform the public of any new and important information as needed.

FDA/NSF/NIH Computer Methods in Cardiovascular Device Design & Evaluation Workshop

The recent FDA report "Challenge and Opportunity on the Critical Path to New Medical Products" describes a looming crisis in the development of medical therapies. To facilitate more effective medical device development, improved engineering analysis methods are needed to predict whether a proposed design will function properly and safely based on the intended function of the device and the anatomic and physiologic data gathered. FDA/CDRH/ODE/DCD along with NSF and NIH are conducting a Workshop on Computer Methods in Cardiovascular Device Design & Evaluation. The purpose of this workshop is to lay important groundwork for the development of optimal computer modeling methods in medical device development. Experts from industry, academia and government will discuss issues in three key areas. First, to document the best-practices and unmet needs in industry and academia related to modeling the cardiovascular system and predicting safety and efficacy of cardiovascular devices. Second, review best practices in other industries in simulation-based engineering sciences including verification and validation. Third, establish a strategy to promote the development, application and validation of computational methods for cardiovascular device design and evaluation identifying the roles of device companies, engineering software companies, academic institutions and government agencies.

Lead Surveillance Process Workshop

Premarket submissions for new pacemaker and ICD leads are almost always leveraged by documentation of good field performance of previous generation leads. Based on recent events with ICD leads, there is concern that the current surveillance processes used to identify problems in the field, and to establish rates for those problems, are not providing timely and complete information. FDA is undertaking an initiative to work with industry and clinicians to study key steps in the surveillance process including clinical evaluation of problems, adverse event reporting, returned product analysis, and post-approval clinical studies. The first step will be for FDA to collect current practice information for these processes from Industry and the clinical community. Next, a workshop with FDA, Industry and Clinicians will be held in September 2008 to review

the current practice information, and to discuss and identify the best practices. The workshop proceeding will be published to document the effort. Participation in this initiative will consist of responding to a questionnaire on current practices and then participating in the workshop. We hope the outcome of this effort will be to promote a more uniform and complete surveillance process leading to earlier and more complete identification of problems in the field, better reporting of information to industry and FDA, and better ability for FDA to make sound pre-market decisions based upon post-market data.

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. In FY 2006, the division underwent a reorganization from 4 to 5 branches realigning product areas to take advantage of shared review responsibilities across reviewers with similar training and education. During the transition of review responsibilities due to the reorganization, DGRND recruited, hired and trained 2 new deputy directors, 3 new branch chiefs, 1 new project manager, and approximately 10 new clinical and scientific reviewers. Our staff rose to these challenges while maintaining the high quality of our regulatory and scientific reviews in meeting the MDUFMA review time goals. In FY 2007, the division undertook a reflective look at its internal and external interactions, its processes and procedures, and its workloads and staffing.

- Leveraging with outside groups

In FY 2006, DGRND began new outreach initiative to industry, academic, clinical and other external groups (beyond our previously established outreach efforts) such as the American Association of Neurological Surgeons, the American Society for Laser Medicine and Surgery, the Society for Interventional Radiology the Orthopaedic Device Forum, the American Academy of Orthopaedic Surgeons, the Orthopaedic Surgical Manufacturer's Association, and the Orthopaedic Research Society. These outreach activities are intended to foster an environment of open communication among representatives of the scientific and clinical community for each of the device types under the review authorities of DGRND. It is our hope that these outreach activities will provide valuable input to DGRND on topics including clinical trial development and conduction, suggestions and development of guidance and voluntary standards for DGRND's consideration, and suggestions for priorities for reclassification, guidance and standards for devices across DGRND. In FY 2007 the division built on its outreach program successes to include interactions with ASPS (American Society of Plastic Surgeons) and presentations to groups such as Controversies and Conversation in Cutaneous Laser and Cosmetic Surgery Meeting, the Cleveland Clinic Grand Rounds,

The International Congress on Computer Assisted Radiology & Surgery, and the American Heart Association International Stroke Conference.

- Expanding our scientific knowledge base

DGRND staff continually seeks opportunities to expand our scientific and clinical knowledge, which greatly enhances our review of innovative technologies. One example is the AAOS/FDA Orthopaedics Seminar Series, founded in 2003. The objective of the group is to organize, facilitate, and share education and training opportunities and experiences related to orthopaedic device products as a means of enhancing and accelerating product review. This year's topic was Orthobiologics – Bone Graft and Beyond. Each seminar involves staff from across the agency, senior level academic researchers and clinicians in the biomedical sciences to discuss emerging scientific and medical theory and clinical practice in an informal setting. Outcomes of the AAOS/FDA Orthopaedic Seminar Series have led to intra- and inter-Center communication and an organized review approach of medical products targeting orthopaedic disorders and conditions. Another example of expansion of our scientific and clinical knowledge is the FDA Neural Interest Group Seminar Series, which through FY 2007 addressed cross-cutting issues that involve CDER and CBER as well as CDRH. Speakers have addressed issues related to various neurological diseases including epilepsy, depression, paralysis and brain tumors. These topics led to discussion of clinical trial designs to address patient needs.

- Reclassification Efforts

DGRND staff continues to challenge themselves to identify and assess device areas that may be appropriate for consideration of reclassification efforts. The latest in this effort was the final rule for Intervertebral body fusion devices (http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-11240.pdf), and NOA for Special Controls Guidance for Intervertebral body fusion devices. 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.

- Public Health Protection/Total Product Life Cycle Efforts

DGRND participated in the PMI action team to address safety concerns regarding the use of metallic tracheal stents for the treatment of benign tracheobronchial strictures; and, off-label use of the device which could cause harm when used in the cardiovascular system. Consequently, the team requested that the indication for benign strictures be removed from the labeling if there was no data to support it. The team also prepared and proposed warning information for the devices labeling to alert the medical community. DGRND is involved in the collaborative reviewer program for CDRH with 8 staff participating in the OSB/ODE efforts and 2 staff participating in the OC/ODE

efforts. The collaborative reviewer program enhances CDRH's ability to regulate devices both pre-market and post-market. In July 2007, the Center released an AFP entitled Advice for Patients: Possible Burns or Fires from Heating Pads manufactured by HoMedics, Inc. This was the result of a recommendation by PMI Action Team (which included members of DGRND) to address issues related to a recall of the powered heating pads from that company.

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

- Outreach to the Public and the Clinical Community

DOED believes that the exchange of knowledge and an improved understanding of the regulatory process by consumers, manufacturers, and health care professionals are critical aspects of our public mission. To that end, DOED staff spent a significant amount of time and resources in FY 06 and 07 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. For the benefit of industry and clinical investigators, DOED staff completed four new device specific guidance documents and was actively involved in the development of 26 standards (ANSI, ISO, ASTM and AAMI).

Our staff provided significant technical input into the maintenance and update of the following ophthalmic and ENT device specific websites for the general public: www.fda.gov/cdrh/LASIK/faq.htm and www.fda.gov/cdrh/cochlear/. In the Contact Lens arena, DOED staff was instrumental in developing the content of a contact lens website (http://www.fda.gov/cdrh/contactlenses/index.html).

Establishment of a Fellowship in Ophthalmic Clinical Trials

DOED partnered with the National Eye Institute (NEI) in establishment of the first fellowship in Ophthalmic Clinical Trials. Fellows will commit themselves full time for 2 years. They will spend equal time at the FDA and NEI, allowing for a unique opportunity to combine knowledge in hands-on clinical trials at the NEI while obtaining regulatory knowledge at the FDA.

By raising awareness of the requirements of regulatory review of safety and efficacy and incorporating them into the schema of development and testing from the early stages, the NEI and the FDA will be better equipped to achieve a common goal: bringing safe and effective ophthalmic devices from the bench to the bedside as quickly as possible.

- Building scientific knowledge through collaborative research

DOED scientists participate in numerous collaborative studies with stakeholders within and outside of the federal government, to improve the premarket review process and to monitor the post approval performance of ophthalmic and ENT devices. Examples of ongoing premarket and postmarket collaborative efforts are described below.

Contact Lens Safety

DOED scientists collaborated with the Chemistry Branch of FDA's Southeast Regional Laboratory in Atlanta and the Division of Healthcare Quality Promotions at the Centers for Disease Control to design and execute a pilot study entitled "Absorption of Alexidine by Contact Lenses and Lens Cases and Its Effect on Disinfection Activity against *Fusarium solani.*" This study provided FDA with its own data on the complex interactions between contact lenses, storage cases and the multipurpose contact lens care solution removed from the market in May 2006. To conduct the study between September and November 2006, a Materials Transfer Agreement (MTA) was established with three contact lens manufacturers to supply materials. A poster was submitted to the May 2007 American Society of Microbiology General Meeting.

DOED continued discussions with the Contact Lens Institute (CLI), a manufacturer trade group, to establish a Cooperative Research and Development Agreement (CRADA) in an effort to re-evaluate the current standard test methods for contact lens disinfecting products. As part of the standards development process, DOED along with OSEL scientists worked with CLI to finalize a preliminary laboratory test of a new method to test contact lens care products. The method exposes a test solution to microbes in a contact lens case that contains lenses to model a real world environment.

MRI Compatibility of ENT devices

ENT staff has been working closely with several sponsors and the CDRH MRI Working Group to define the appropriate bench studies and/or clinical studies necessary to support MRI compatibility indications for cochlear implant devices. This work has, in particular, focused on the assessment of electrode heating and unintended stimuli during MRI procedures, and how proper procedures for specific implant designs/manufacturers during MRIs could be conveyed to MRI centers.

Critical Path Project: Driving Simulation Study

Senior review scientists in DOED continued the 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 objective of the outreach project is to determine correlations between clinical tests of visual/optical quality and visual performance in night driving conditions with the goal of finding a surrogate for functional performance.

This study has been completed and initial data analysis conducted. These results were presented at the 2007 meeting of the Association for Research in Vision and Ophthalmology. Extensive data analysis is ongoing.

As part of this critical path initiative, the DOED investigators reviewed efforts to identify reliable, cost-effective clinical tests to serve as surrogate measures of functional visual performance when evaluating how medical products affect vision. This review was published as an article, "Assessment of Visual Performance in the Evaluation of New Medical Products," in *Drug Discovery Today: Technologies* (Vol. 4, Issue 2, pp. 55-61, Winter 2007). This article was included in a special Critical Path section edited by Dr. Janet Woodcock, then Deputy Commissioner and Chief Medical Officer of the FDA, and currently Director, Center for Drug Evaluation and Research.

This critical path initiative will expand ODE's regulatory science base and assist ODE in developing a least burdensome approach in the approval of ophthalmic devices through the use of better evaluation tools.

International Club for Biomaterials and Regenerative Medicine in Ophthalmology

DOED review scientists continue to participate and have an active 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. At the March 17, 2006 meeting, the Club provided a forum to explore novel advances such as a photochromic intraocular lens (IOLs) which will respond to the level of UV light exposure; surface modified IOLs to deliver drugs; elastomeric hydrophobic acrylic polymers for ophthalmic applications; injectable lens materials capable of providing accommodation, etc. These examples are merely a sampling of the unique and innovative developments discussed at the ICBRO meeting. The April 27, 2007 meeting will introduce even more biomaterial innovations and explore ongoing biomaterial issues.

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

The Division of Reproductive, Abdominal, and Radiological Devices reviews a wide variety of medical devices such as biliary stents, condoms, fetal monitors, hemodialysis equipment, radiation treatment planning systems, incontinence devices, tampons, obesity treatment devices, and diagnostic imaging systems. The division staff focused on meeting 4 major challenges for FY 06 and FY 07: meeting MDUFMA goals; communicating within and outside of the division; postmarket activities; and meetings with sponsors.

We introduced a new meeting procedure, specifically, the receipt of a background package from the sponsor prior to scheduling a meeting. We believe that the procedure has improved the timeliness, efficiency, and productivity of our meetings. The division has been diligent in its internal, pre-meeting preparations. During the pre-meeting, the FDA attendees draft responses to the questions posed by the sponsor in the background package, as well as compile additional comments to be communicated to the sponsor during the meeting. We believe preparation on the part of the division as well as the sponsor is the key to successful meetings.

Condom Labeling Review Initiative

The Obstetrics and Gynecology Devices Branch (OGDB) continued to work on the evaluation of condom labeling for "medical accuracy." Following up public comments on the 2005 Notice of Proposed Rule Making and draft guidance document, a Center-wide review team designed and received approval to conduct a two-phase label comprehension study, whose purpose is to evaluate/address issues around understandability of current and proposed condom consumer labeling. This was undertaken to address concerns expressed in public comments that the proposed language was confusing and misleading. Phase I of the study was completed in December 2007. In parallel, work continued on addressing the rest of the comments and any new published studies for the Preamble to the final rule.

Biliary Stents

The Gastroenterology and Renal Devices Branch (GRDB) is responsible for the review of marketing applications for biliary stents. Over the past several years, FDA has become increasingly concerned about the off-label promotion and use of expandable metal biliary stents within the peripheral vascular system. When labeled for the palliation of malignant neoplasms, biliary stents are reviewed as Class II (510(k)) devices in submissions containing primarily in-vitro bench testing. In contrast, vascular stents are reviewed as PMA submissions, with additional pre-clinical testing and clinical studies. Because of FDA's concerns regarding off-label use, since 1999 manufacturers marketing expandable biliary stents have been required to prominently display the biliary indication in all labeling and to include a warning stating that the device's safety and effectiveness in the vascular system have not been established. Over the past 5 years, FDA has noticed an increase in the number of Medical Device Reports (MDRs) being submitted for biliary stents used off-label. The reports have included malfunctions and serious injuries, including deaths resulting from vessel structural damage and cardiac arrhythmias and infarctions.

Based on FDA's concerns, a Center-wide Postmarket Issue (PMI) Action Team was convened. The action items from this PMI Action Team were numerous, including the convening of an industry-wide meeting with the Center Director to address off-label promotion of biliary stents; a review of all promotional material from biliary stent manufacturers, with continued surveillance and periodic review; increased scrutiny of

510(k)s for biliary stents, especially regarding performance testing and stent/delivery system dimensions and styles; increased requirements for clinical testing of new devices that are "outside the box" of biliary stent sizes and styles already cleared; and further clarification of the SE with Limitations warning and labeling restrictions for biliary stents. It is hoped that continued efforts on the part of FDA, including encouraging manufacturers and physicians to support and conduct appropriate clinical trials to assess the safety and effectiveness of expandable metal stents in peripheral vasculature locations, will result in a decrease in the use of biliary stents off-label and fewer adverse event reports.

Standards Development for Urology and Lithotripsy Devices

A Urology and Lithotripsy Devices Branch (ULDB) employee attended an IS0 standards meeting regarding endoscopes in Xiamen, China. Discussions covered the cross reference of Global Medical Device Nomenclature (GMDN) with terms and definitions for endotherapy devices; reconfirmation of IS0 8600-2 and IS0 8600-4; development of a standard for capsule endoscopy; revision of IEC 60601 Part 2-18: Particular requirements for basic safety and performance of endoscopic equipment; and the impact of the CEN/BT TF 123 standard for Luer connectors on endoscopes.

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.

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.

Leadership Readiness Program

In FY 06, ODE initiated a Leadership Readiness Program to create a pool of employees with skills necessary for transitioning into projected first-level supervisory vacancies within the Office.

This one year cohort program includes training in conflict resolution, facilitation, group dynamics, FDA administrative policies, and communication skills. Participants have also been provided several opportunities for learning about themselves through assessment instruments such as Myers-Briggs, Emotional Intelligence, and a 360 profile.

Each participant was also matched with a mentor from ODE or OIVD who individually assists their mentoree (participants) to identify crucial developmental opportunities that will enhance their learning and provide skills that cannot be learned in the classroom.

Thirteen employees from ODE and three employees from OIVD were competitively selected to participate in the program. Fourteen ultimately completed the program, and five of those individuals have been promoted into permanent management positions at CDRH. This ODE/OIVD program was so successful in developing our future leaders that it has been adapted for use in all of CDRH.

ODE Staff Receive Outside Honors

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

DAGID Awards and Special Recognition:

Harry Sauberman received the IEEE Washington Section 2005 Volunteer-of-the-Year Award for his work with the University of Maryland graduate engineering students.

William M. Burdick has been accepted for inclusion in the 2007 edition of Marquis' Who's Who in America.

DGRND Awards and Special Recognition:

During FY 06, Binita Ashar, M.D., M.B.A., of the General Surgical Devices Branch served as an Advisor for Medicine and Public Health for Homeland Security Affairs in the Office of the Vice President for the United States. Dr. Ashar's service was honored with appreciation letters from the Chief of Staff to the President, Mr. Andrew Card, and, the other from Vice President Dick Cheney.

DOED Awards and Special Recognition:

Teresa Cygnarowicz received her doctorate degree in audiology (AuD) from the Pennsylvania College of Optometry-School of Audiology on April 16, 2006.

Bruce Drum is in the 2007 edition of Marquis' Who's Who in America (61st Edition, Marquis' Who's Who LLC, Providence, NJ).

DRARD Awards and Special Recognition:

Ewa Czerska, MD, Ph.D., is president of the Bioelectromagnetic Society (BEMS) for 2007-2008.

Gema Gonzalez, as a member of the Renal Diseases and Detoxification Committee, received an AAMI Standards Technical Committee Award in 2007.

Raju Kammula, DVM, Ph.D., was commended for his long service to the American Veterinary Medical Association (AVMA) on July 15, 2006.

Pam Weinel, RN, MS, MBA, was accepted for inclusion in the 2005-2006 editions of Marquis' Who's Who in American Women and in the 2006-2007 editions in Who's Who in Medicine and Healthcare.

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 06 and FY 07, ODE staff members continued their efforts in international outreach and global harmonization activities. Several staff served on the Global Harmonization Task Force (GHTF). Their efforts were directed towards harmonizing medical device regulation on a global basis. In addition, the office participated in several meetings with government regulators, academicians and representatives from many countries. These meetings, hosted by DSMICA, included:

In FY 06 --

(1) Health Canada – Regulations for Single Use Devices – March 16, 2006;

(2) China, Jiangsu Province, Food and Drug – Premarket Regulatory Processes – May 17, 2006; and

(3) China, Jiang Test and Research Institute for the Control of Medical Devices – Devices 101 and Specifically Contact Lenses – June 2006.

In FY 07 –

(1) Taiwan, National Cheng Kung Univ. – Innovation and Development of Medical Devices – Feb. 5–7, 2007;

(2) Singapore, Health Science Agency – Overview of Medical Device Regulations – June 13, 2007.

Part 4 – Major Program Initiatives

PANDEMIC AND AVIAN INFLUENZA

I had a little bird
Its name was Enza
I opened the window
And in-flu-Enza*

(*A rhyme recited by children while jumping rope during the 1918 influenza pandemic. It can be found at: "The 1918 Influenza Pandemic" @http://virus.standford.edu/)

As the density of the world population increases, we are ever faced with diseases of global proportion. In 1918-1919, the world experienced an influenza pandemic which killed 20-40 million people worldwide. Today most experts believe that we are on the brink of another pandemic of global impact. The possible source of a pandemic may be avian influenza caused by the highly pathogenic H5N1 (HPH5N1) virus. To that end there has been much activity going on at the Department of Health and Human Services (DHHS) to develop strategies that can be implemented if such a scourge happens again. DAGID staff have been actively sought after to participate on committees working on influenza and pandemic issues, and to review numerous documents on emergency preparedness and pandemic issues. The meetings are both within the Department of Health and Human Services involving several agencies such as the FDA and the Centers for Disease Control and Prevention; and, inter-departmental including the Department of Homeland Security and Department of Labor. The documents reviewed come from The White House, Department of Labor, Department of Homeland Security, Department of Agriculture, the Environmental Protection Agency, Department of Education, Institute of Medicine and many others.

Many of the medical devices reviewed by DAGID staff play an integral role in both the minimization of exposure to infectious agents and the delivery of treatment modalities for those who are ill. These include personal protective equipment such as surgical gowns, surgical masks and surgical N95 respirators, gloves, sterilants and high level disinfectants, ventilators, oxygen concentrators, and even needles, syringes and intravascular equipment which will be needed in great quantities during either a natural or man-made disaster.

PROGRAM FOR ASSESSING THE QUALITY OF PREMARKET REVIEW MEMOS

In FY 06 and FY 07, the Office of Device Evaluation continued, and expanded, its program to assess the quality of the documentation within review memos for premarket

submissions. The program began in FY 05 with two scientific elements common to many premarket submissions - biocompatibility and sterility/packaging. Since then, two additional review areas have been added – software (FY 06) and clinical (FY 07). Teams consisting of subject matter experts in each scientific area were assembled from across CDRH Offices. Each team created a set of "critical review elements" which were deemed essential for documentation or inclusion in a review related to that area. These elements were used to assess the quality of review memos from randomly selected 510(k)s (or IDEs for the clinical team) and PMA submissions with recent final decisions. Teams were scheduled to participate in two assessment rounds per year.

- Sterility Assessments

We have completed three rounds of assessments of quality issues in terms of documentation of sterility review. Some quality review issues were noted. In response, division focal points were identified to provide assistance to reviewers in the divisions. In addition, ODE staff conducted a Staff College course (December 2006) and created a review checklist (April 2007) to educate and assist reviewers in performing sterility reviews. A fourth round of assessment, following implementation of these interventions, showed a marked improvement in the quality of review memos.

The Office will continue to assess the results of sterility reviews over the coming year to measure the impact of our interventions.

- Biocompatibility Assessments

A total of 4 rounds of biocompatibility document review have been completed through 2007. Some quality review issues were noted.

In response, a biocompatibility review checklist was developed by the assessment team and will be introduced to the ODE review divisions in 2008. A Staff College course for performing biocompatibility reviews will be offered in 2008 as well. The Office will assess the impact of these interventions in future assessment rounds once they are implemented.

- Software Assessments

Three assessment rounds have been completed for software reviews through 2007. Some quality review issues were also noted.

The software assessment team identified focal points for each of the review divisions and in 2008 will be creating a reviewer template for completing software review. A training

course for basic software review will also be developed for pre-market reviewers to improve the quality of the review documentation.

- Clinical Assessments

Through 2007 the clinical team (the newest team) has completed an initial assessments of IDE clinical review memos. The Office will continue to assess the results of software reviews over the coming year.

The clinical team will continue to gather data on IDE and PMA review memos during the coming year.

TRANSFER OF POST-APPROVAL STUDY RESPONSIBILITIES

FY 06 and FY 07 saw the creation and implementation of a Memorandum of Understanding for the transfer of post-approval study (PAS) responsibilities from ODE to the Office of Surveillance and Biometrics (OSB). During this time, epidemiologists from OSB have been consistently consulted for original and panel-track PMA submissions received by ODE. The epidemiologists are now included as integral parts of the PMA review team at the early stages, focusing their efforts on interacting with ODE staff and device sponsors in determining appropriate post-market clinical study questions and developing the PAS to adequately address these issues. As part of this initiative, epidemiologists from OSB have participated in several Advisory Panel meetings as part of the FDA team, making presentations regarding the proposed PAS for the application under consideration. They have also been providing updates to Panels with regards to the status of on-going PAS. In addition, during this time OSB has assumed responsibility from ODE for reviewing and responding to PMA reports for PAS.

During FY 06 and FY 07, with the assistance of ODE staff, OSB populated its new electronic database (COATS – Conditions of Approval Tracking System) to track the status of all PAS ordered as a Condition of Approval. This database, which is now fully operational, allows CDRH to notify sponsors if and when PAS reports are due or overdue. Certain data from this tracking system are also now made available to the public on CDRH's website.

ODE COLLABORATIVE REVIEWER PROGRAM

In 2007, ODE, in conjunction with the Office of Surveillance and Biometrics, launched the ODE-OSB Collaborative Reviewer Program as part of CDRH's Postmarket Transformation initiative. The pilot program, which began in March, was intended to facilitate and encourage communication between pre- and post-market programs.

Twenty-three (23) reviewers from ODE were selected and trained to participate in the program. In addition to their regular pre-market review duties, these reviewers are spending approximately half of their time performing traditional post-market surveillance activities including review and analyses of Medical Device Reports (MDRs). It isanticipated that having staff simultaneously performing pre- and post-market activities for a particular set of medical device products will benefit the Center in several ways. These include earlier detection of post-market signals, using real-world post-market information as feedback to improve pre-market review of similar or later generation products, as well as bringing a unique perspective to the interpretation and evaluation of post-market events based on familiarity with the premarket history of the device or device type. This program will continue throughout 2008.

LEVERAGING IT SYSTEMS FOR INCREASED EFFICIENCY

ODE continued to pursue development of new IT systems for improved tracking and monitoring of submissions. We review our current systems and consider the infrastructure needs required to move toward electronic submissions.

- Electronic Copies

In FY 06, ODE received 262 complete electronic copies of submissions for original PMAs, IDEs, and 510(k)s in addition to the paper submission. These numbers show an increase from FY 04 when 74 electronic copies were received. In FY 07, the number of complete electronic copies of submissions continues to increase to almost 800.

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.

- Information Systems For Document Tracking And Archiving

Numerous enhancements were made to information systems used by ODE during FY 06. The acknowledgement letters for all application types were modified to include electronic copy information. The CDRH electronic copy initiative encourages all manufacturers to submit electronic copies along with the paper submission whenever possible. The PMA data entry program was modified to capture the new annual report calculation, and the premarket letters were changed to work on the new printers. The premarket databases were updated due to the ODE/DGRND reorganization, and the premarket data was reviewed in support of the design and development of the premarket data warehouse.

In FY 07, the CDRH Ad hoc Reporting System (CARS), which provides a data warehouse and business intelligence portal for extensive reporting and analysis of CDRH data, had two major releases. The first release of CARS contained primarily 510(k) data. The second release was in support of MDUFMA and provided MDUFMA reports for 510(k), PMA, and Modular PMA submissions as well as supporting ad hoc queries of 510(k), PMA, Modular PMA, and 513g data.

The Center Tracking System (CTS) was modified to include an Interactive Review Log feature in support of MDUFMA and to include additional enhancements to display MDUFMA due dates. The combination product flag was added to CTS to allow reviewers to set the value for that field and changes were made to the PMA and 513g data entry programs in support of MDUFMA. The premarket applications were also modified in order for those applications to link to FURLS (FDA Unified Registration and Listing System).

- Improved Communication and Interaction Tools For PMA Review Teams

ODE continued to use eRoom to facilitate communication and interactions among team members in the review of PMAs. In FY 07, we continued to create eRooms to store documentation related to the review of individual ODE and OIVD original PMAs and panel-track supplements. PMA team members are using the eRoom template to organize and save letters, review memos, meeting documentation, and email throughout the PMA review.

In addition, ODE created a general PMA eRoom that is used by CDRH as a primary source of documents related to PMAs. The PMA eRoom includes boilerplate letters for ODE, OIVD, OC, and OSB. It also includes key staff memos and emails, spreadsheets, links to guidances, internal procedures, etc.

Both the eRooms for each individual PMAs and the general PMA eRoom have improved the efficiency and consistency of PMA reviews.

As a result of the success with the PMA eRoom, this same concept was applied to all the premarket programs and was expanded to include 510(k), IDE, and HDE programs.

- Hardware Upgrades

ODE purchased replacement laptop computers for the remaining staff on board in FY 06 and for some new employees who arrived in FY 07. ODE continued to upgrade its equipment infrastructure with the purchase of facsimile machines, replacement printers for secretaries, consumer safety technicians and the document control center employees, shared color laser printers, scanners for travel preparers, and LCD projectors for meetings. There were no significant computer hardware upgrades in FY 07.

THE DEFIBRILLATION WORKING GROUP (DWG)

The Defibrillation Working Group (DWG) has been an important focus of DCD and Center activities. The group is composed of representatives from each of the Offices within CDRH, primarily representing front-line staff and some managers. A Steering Committee comprised of senior managers within the Center provides oversight to the working group.

The DWG has created several mechanisms to improve internal communication among Center experts dealing with implanted pacemakers and defibrillators. Members of the group have tackled issues such as improving the content of PMA Annual Reports, developing a guidance document for Dear Doctor letters, and improving how we communicate with external stakeholders like the media and Congress. Some efforts, such as the creation of a Postmarket Advisory Panel, can be considered near completion, while others, such as the MedSun Heart Network, are part of a larger Center effort for which the DWG is providing necessary expertise.

COMBINATION PRODUCTS

Combination products, consisting of devices and drugs or devices and biologics, continued to be a focus of effort for ODE. In FY 06, 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 06, ODE reviewed 28 Requests for Designation (RFDs), 19 for device-drug combinations, 5 for device-biologic combinations, 1 for a drug-device-biologic combination, and 3 RFDs were determined to be non-combination device products. CDRH was given the lead for 18 of these. We also reviewed and acted on premarket applications for 139 new combination products. Our device expertise was called upon frequently by our sister centers and we performed 95 consulting reviews.

In FY 07, ODE reviewed 31 RFDs, 26 for device-drug combinations, 3 for device-biologic combinations, and 2 for drug-device-biologic combination. In FY 07, we reviewed and acted on premarket applications for 148 new combination products. Our device expertise was called upon frequently by our sister centers and we performed 120 consulting reviews.

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

Autoinjector Working Group
Cardiovascular Products Working Group
Cartilage Repair Group
CBER/CDRH Tissue Engineering Steering Committee
DHHS Joint Working Group on Telemedicine
FDA RFID Team

Interagency Blood Glucose Closed Loop Working Group
Interagency CWD Decontamination Working Group
Interagency Oncology Task Force Y
Multi-Agency Tissue Engineering Science (MATES) Interagency Working Group (IWG)
Orthopedic Indications Working Group
Tissue Engineering Working Group (FDA, NIH, NIST, NASA, DOE)
Tissue Policy Team
Tissue Reference Group
Wound Healing Clinical Focus Working Group
Wound Care Solutions Working Group

ODE Device Guidance Documents

In FY 06, ODE issued 15 guidance documents, 8 Level 1 and 7 Level 2, which are listed below. Among the 15, 7 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 13 was developed in collaboration with Office of Science and Engineering Laboratories (OSEL). 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	FOD#	Date	Links
Guidance for Industry and FDA Staff - Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices	ODE	1216	09/25/2006	Text PDF
Guidance for Industry and FDA Staff - Keratome and Replacement Keratome Blades Premarket Notification [510(k)] Submissions	ODE/DOED/DSDB	1604	09/18/2006	Text PDF
Guidance for Industry and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers	ODE/ODEOD/POS		07/18/2006	Text PDF
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Olfactory Test Device	ODE/DOED/ENTB	1595	06/07/2006	Text PDF
Topical Oxygen Chamber for Extremities - Class II Special Controls Guidance Document - Draft Guidance for Industry and FDA Staff	ODE/DGRND/PRSB		04/06/2006	Text PDF
Guidance for Industry and FDA Staff: Tonometers - Premarket Notification [510(k)] Submissions	ODE/DOED/DSDB	1593	03/27/2006	Text PDF
Dental Curing Lights - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff	OSEL/DPS ODE/DAGID/DEDB	1591	03/27/2006	Text PDF
Implantable Intra-Aneurysm Pressure Measurement System - Class II Special Controls Guidance Document	ODE/DCD/PVDB	1589	02/15/2006	Text PDF
Bone Sonometers - Class II Special Controls Guidance Document - Draft Guidance for Industry and FDA Staff	ODE/DRARD/RDB	1547	02/15/2006	Text PDF
Draft Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device	ODE/DGRND/ORDB	1540	02/09/2006	Text PDF
A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff	ODE	1347	11/10/2005	Text PDF
Tinnitus Masker Devices - Class II Special Controls Guidance Document - Draft Guidance for Industry and FDA Staff	ODE/DOED/ENTB	1555	11/08/2005	Text PDF
Low Energy Ultrasound Wound Cleaner: Class II Special Controls Guidance Document - Guidance for Industry and FDA Staff	ODE/DGRND/PRSB	1302	11/07/2005	Text PDF

Document Name	Off/Div/Br	FOD#	Date	Links
Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff	ODE/DAGID/DEDB	642	10/26/2005	Text PDF
Draft Guidance for Industry and FDA Staff - Functional Indications for Implantable Cardioverter Defibrillators	ODE OC	1304	10/06/2005	Text PDF

ODE Device Guidance Documents

In FY 07, ODE issued 12 guidance documents, 9 Level 1 and 3 Level 2, which are listed below. Among the 12, 6 are Special Controls guidance. These guidance documents and other previously issued guidance documents are available on the World Wide Web (CDRH homepage: http://www.fda.gov/cdrh) which provides easy access to the latest information and operating policies and procedures. They may also be obtained from the Division of Small Manufacturers International and Consumer Assistance (DSMICA, HFZ-200). To contact DSMICA, call 800-638-2041; 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	FOD#	Date	Links
Guidance for Industry and FDA Staff - Non-clinical Information for Femoral Stem Prostheses	ODE/DGRND/ORDB		09/17/2007	Text PDF
Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology	ODE/DGRND/PRSB	1629	08/03/2007	Text PDF
Draft Guidance for Industry and FDA Staff - Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents	ODE	1557	07/19/2007	Text PDF
Draft Guidance for Industry and FDA Staff - Pulse Oximeters - Premarket Notification Submissions [510(k)s]	ODE/DAGID/ARDB	1605	07/19/2007	Text PDF
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies	ODE/DAGID/INCB	1626	07/03/2007	Text PDF

Document Name	Off/Div/Br	FOD#	Date	Links
Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin	ODE/DGRND/PRSB	1630	07/03/2007	Text PDF
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device	ODE/DGRND/ORDB	1540	06/12/2007	Text PDF
Guidance for Industry and FDA Staff: Dental Handpieces - Premarket Notification [510(k)] Submissions	ODE/DAGID/DEDB	556	05/02/2007	Text PDF
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems	ODE/DRARD/OGDB	1625	04/24/2007	Text
Guidance for Industry and FDA Staff - Saline, Silicone Gel, and Alternative Breast Implants	ODE/DGRND/PRSB	1239	11/17/2006	Text PDF
Draft Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Absorbable Hemostatic Device	ODE/DGRND	1558	10/31/2006	Text PDF

Reclassification Petitions

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

Proposed Reclassification Actions – FY 06 and FY 07

Published a proposed rule in the Federal Register on February 15, 2006, to reclassify bone sonometer devices from class III (premarket approval) into class II (special controls).

Published a proposed rule in the Federal Register on February 9, 2006, to reclassify intervertebral body fusion devices that contain bone grafting material from class III (premarket approval) into class II (special controls) and retain those that contain any therapeutic biologic (e.g., bone morphogenic protein) in class III (premarket approval).

Published a proposed rule in the Federal Register on April 6, 2006, to reclassify topical oxygen chamber for extremities (TOCE) from class III (premarket approval) into class II (special controls).

Published a proposed rule in the Federal Register on October 31, 2006, to reclassify the Absorbable Body Fusion Device form class III (premarket approval) into class II (special controls).

Published a proposed rule in the Federal Register on July 3, 2007, to reclassify the Tissue Adhesive for Topical Approximation of Skin Device from class III (premarket approval) into class II (special controls).

Final Reclassification Petition – FY 07

Published a final rule in the Federal Register on June 12, 2007, reclassifying the Intervertebral Body Fusion Device from class III (premarket approval) into class II (special controls).

Denial of a Reclassification Petition – FY 06 and FY 07

Published a denial in the Federal Register on July 14, 2006, regarding a request of change in classification of the breathing frequency monitor and the electroencephalograph from class II (special controls) to class I (general controls).

Published a notice of denial in the Federal Register on July 3, 2007, for a change in classification of the Impedance Plethysmograph from class II (special controls) to class I (general controls).

Published a notice of denial in the Federal Register on July 3, 2007, for a change in the classification of the Cutaneous Electrode from class II (special controls) to class I (general controls).

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 06, 9 MDAC panel meetings were held. These panels reviewed and made recommendations on 6 PMAs, 10 preamendment device classifications, 1 Over-the-Counter (OTC) designation and 2 general issues. The MDAC panels reviewed PMAs for

significant device breakthrough technologies such as a first of a kind cervical disk replacement which was also the first metal-on-metal articulation in the spine.

In FY 06, there were 8 training sessions for new MDAC panel members and consultants. At 3 of the MDAC meetings there were briefings on the new postmarket study design and follow-up procedures introduced on January 1, 2005, and at 3 ODE meetings the Agency's Critical Path Initiative was outlined.

In FY 07, 14 Medical Device Advisory Panel meetings were convened for a total of 17 days. These panels reviewed and made recommendations on 11 PMAs, 1 premarket notification [510(k)], and 5 general issues. The panels reviewed PMAs for significant device breakthrough technologies such as a first of a kind non-constrained, mobile-bearing ankle prosthesis and a novel cervical disk prosthesis for patients with degenerative disk disease. The Circulatory System Devices Panel was convened to seek expert advice regarding postmarket safety issues with drug-eluting stents. Seven training sessions for new panel members were held in FY 07.

Two Medical Device Dispute Resolution Panel meetings were held in response to sponsor requests in December 2006 and April 2007. The Dispute Resolution Panel reviews scientific disputes between FDA and the sponsor. The panel provides a recommendation to the Center Director.

As part of the Center's Postmarket Transformation, epidemiologists from the Office of Surveillance and Biometrics (OSB) participated in the review and the FDA presentation addressing the proposed post approval study plans submitted by device sponsors at 7 of the PMA meetings during FY 07. Additionally, updates of two post approval studies in progress were presented to the Advisory panel by both OSB and the device sponsors.

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 www.fda.gov/oc/advisory/vacancies/acvacmain.html.

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 6 ODE panels of the Medical Devices Advisory Committee met during FY 06:

Dental Products
General and Plastic Surgery
Obstetrics and Gynecology
Ophthalmic
Orthopaedic and Rehabilitation
Radiological

The following 7 ODE panels of the Medical Devices Advisory Committee met during FY 07:

Dental Products
Immunology
Circulatory Systems
Dispute Resolution
Neurology
Orthopaedic and Rehabilitation
General Hospital

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

ODE/OIVD Application Integrity Program

Under the Application Integrity Program, ODE/OIVD considered many cases concerning the integrity of data submitted to the agency in premarket submissions. During FY 06, we managed 50 potential or actual cases and during FY 07 we had 54 such cases.

During 07, we issued two Integrity Hold (IH) letters.

FDA removed IH restrictions from two firms during FY 06. During FY 07 we removed IH from three medical device manufacturers and similar restrictions from another firm that was not officially on IH.

In managing this program, we reviewed many major documents including inspectional findings, data audits, system audits, and corrective action plans for cases in process.

Our staff also worked with the Office of Criminal Investigation (OCI) on various data integrity cases and issues.

Part 5 – Key Performance Indices

Historically, the ODE Annual Report has included combined data for both ODE and OIVD. The FY 05 Annual Report was the first report that included only data for ODE. In this part, first, we present the major submissions[1] received in ODE from FY 97 to FY 07. 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 06 and FY 07 (known as "the decision cohort").

Major Submissions Received

As shown in Table 1, during FY 06, ODE received 9,415 major submissions, up from 8,690 in FY 05. This increase is primarily due to an increase in the total number of PMA supplements received. In FY 07, the number received went down to 9,276.

Of the 25 original PMAs and 21 panel track supplements received in FY 06, 2 were granted expedited status. Of the 31 original PMAs and 4 panel track supplements received in FY 07, 2 were granted expedited status. Similarly, 2 original and PMA panel track supplements received expedited status in FY 06. In FY 07, 18 of the 31 (58%) original PMAs were submitted as modular PMAs as compared to 11 (44%) modular PMAs submitted in FY 06.

Of the 1,113 PMA supplements received in ODE in FY 06, 212 were categorized as 180-day PMA supplements, up from 169 in FY 05. Of the 1,087 PMA supplements received in ODE in FY 07, 234 were categorized as 180-day PMA supplements, up from 212 in FY 06. The number of fee paying 180-day supplements, remains fairly stable between FY 07 (130) compared to FY 06 (128).

A total of 277 requests were received and processed for real-time PMA supplements in FY 06, up from 184 in FY 05. Of those submissions, 252 were approved. Most applicants chose telephone conferencing versus a face-to-face meeting or a video conference. The majority of these applications were reviewed in DCD (78%) followed by DGRND (11%), DOED (6%), DAGID (3%), and DRARD (2%).

A total of 256 requests were received and processed for real-time PMA supplements in FY 07, slightly down from 277 in FY 06. Of those submissions, 237 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 (79%) followed by DGRND (9%), DRARD (6%), DOED (5%), and DAGID (1%).

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

In addition to 180-day and real-time supplements, CDRH also received 521 30-day notices/135-day supplements in FY 06, a significant increase from the number of 30-day notices/135-day supplements received in FY 05 (281). This increase is primarily due to an increase in the number of manufacturing changes associated with cardiovascular devices. CDRH received 530 30-day notices/135-day supplements in FY 07, a slight increase from the number of 30-day notices/135-day supplements received in FY 06 (521).

Of the 3,240 510(k)s received in FY 06, 2,385 were submitted as traditional 510(k)s, 130 were submitted as abbreviated 510(k)s, and the remaining 725 were Special 510(k)s.

Of the 3,192 510(k)s received in FY 07 2,402 were submitted as traditional 510(k)s, 166 were submitted as abbreviated 510(k)s and the remaining 624 were Special 510(k)s.

No 510(k)s were granted expedited status in FY 06 and one 510(k) was granted expedited status in FY 07.

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. Two hundred and forty-four 513(g)s were received in FY 06 and 381 were received in FY 07.

ODE received approximately the same number of original IDEs and IDE supplements between FY 06 and FY 07. In FY 07, ODE received and processed 211 original IDEs and 4,345 IDE supplements as compared to 251 original IDEs and 4,485 IDE supplements in FY 04.

In FY 07, the number of original HDEs received was 6, up from 4 in FY 06. The number of HDE supplements received decreased from 53 in FY 06 to 23 in FY 07.

Table 1. Major Submissions Received
FY 97 – FY 07

TYPE OF SUBMISSION	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	2006 ODE Only	2007 ODE Only
Original PMAs	66	48	64	67	71	49	54	37	43	25	31
PMA Supplements	409	517	557	546	641	645	666	565	712	1,113	1,087
Original IDEs	297	322	304	311	283	312	242	222	226	251	211
IDE Supplements	3,776	4,277	4,127	4,388	4,810	4,722	4,415	4,297	4,264	4,485	4,345
510(k)s	5,049	4,623	4,458	4,202	4,248	4,320	4,247	3,107	3,130	3,240	3,192
Original HDE	4	8	12	11	5	5	10	9	4	4	6
HDE Supplements	0	0	4	10	16	16	29	28	24	53	23
513(g)s	29	34	43	59	82	104	156	239	287	244	381
Total	**9,630**	**9,829**	**9,569**	**9,594**	**10,156**	**10,192**	**9,819**	**8,504**	**8,690**	**9,415**	**9,276**

ODE Review Performance

- Premarket Approval Applications (PMAs)

The figures below provide the ODE review performance for PMAs filed in FY 01 to FY 06. The data for FY 07 was not included because a significant number of PMA submissions received in FY 07 are still under review and a final decision has not been issued. (The data for FY 07 will be presented in the next ODE annual report.)

As shown in Figure 1, the average total elapsed time for original PMAs and panel track PMA supplements has decreased overall from FY 03 to FY 06. The increase in FY 05 is likely due to a staffing shortage that occurred in 2005 due to uncertainties over the continuation of the Medical Device User Fee Program.

As shown in Figure 2, this trend for a decrease in total elapsed time has not been accompanied by a consistent decrease in FDA total time.

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

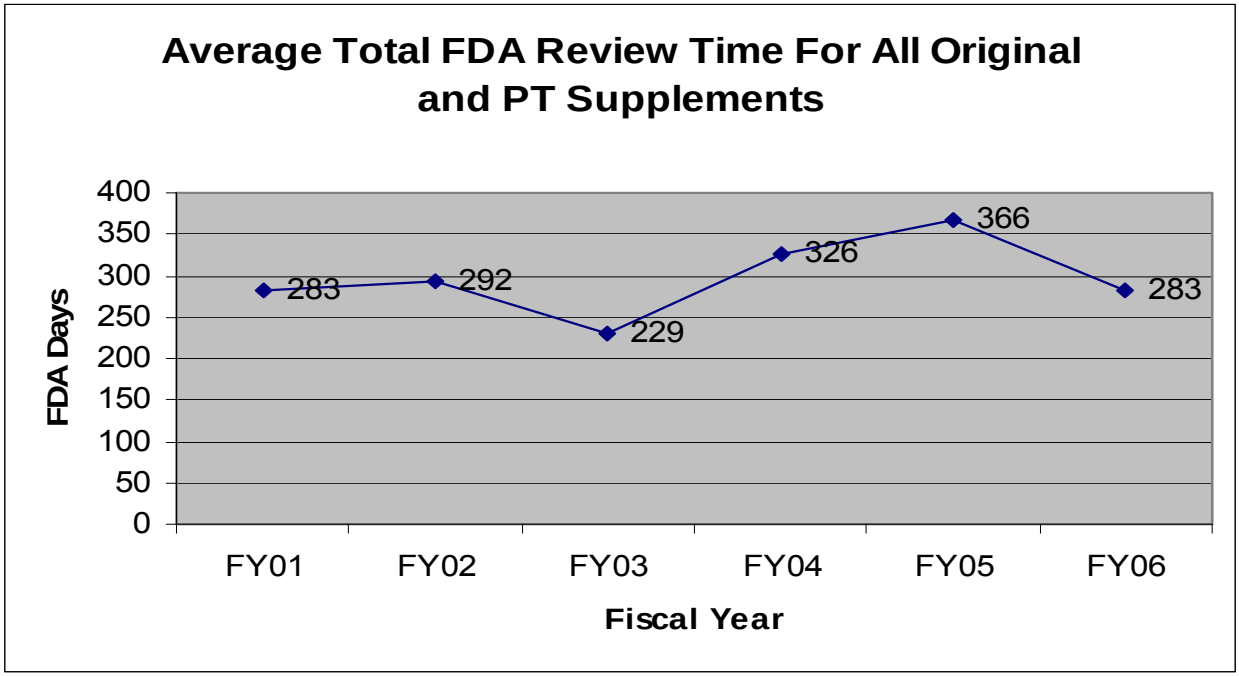


Figure 2: Average Total Elapsed Days from Filing to Approval (excluding withdrawals) for All Original and Panel Track PMA Supplements

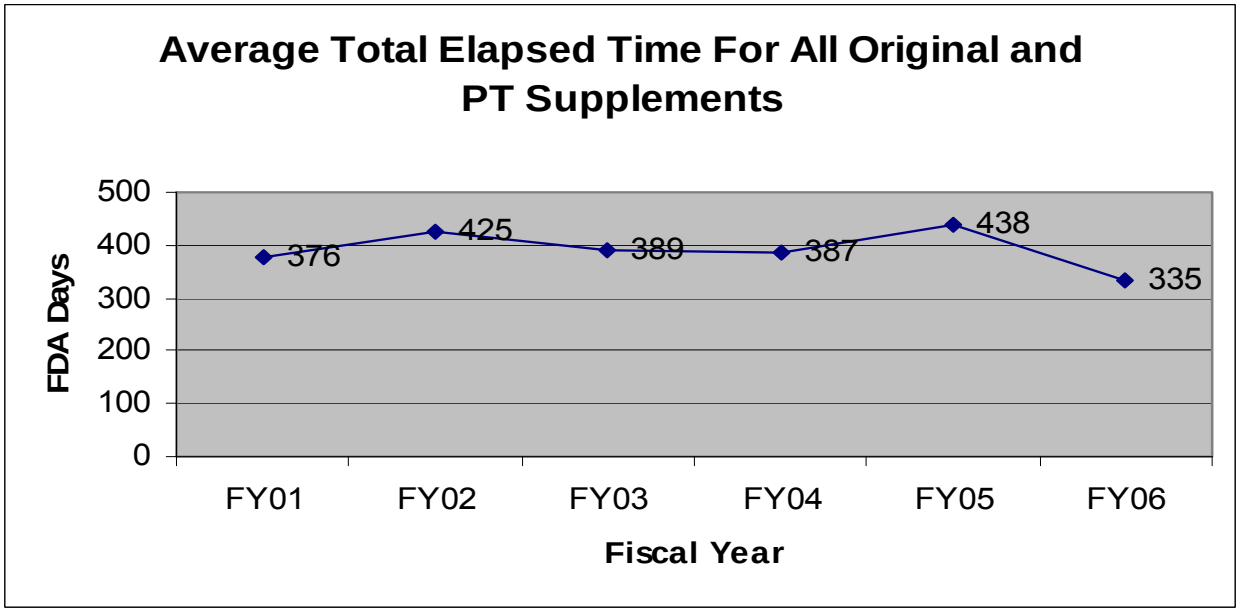
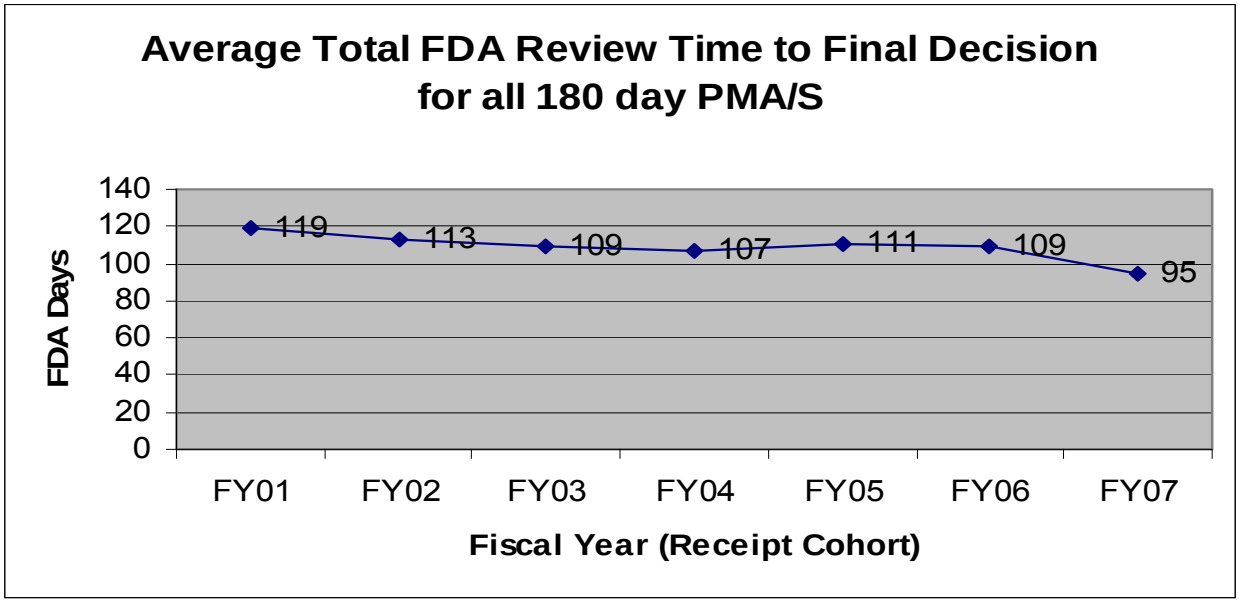


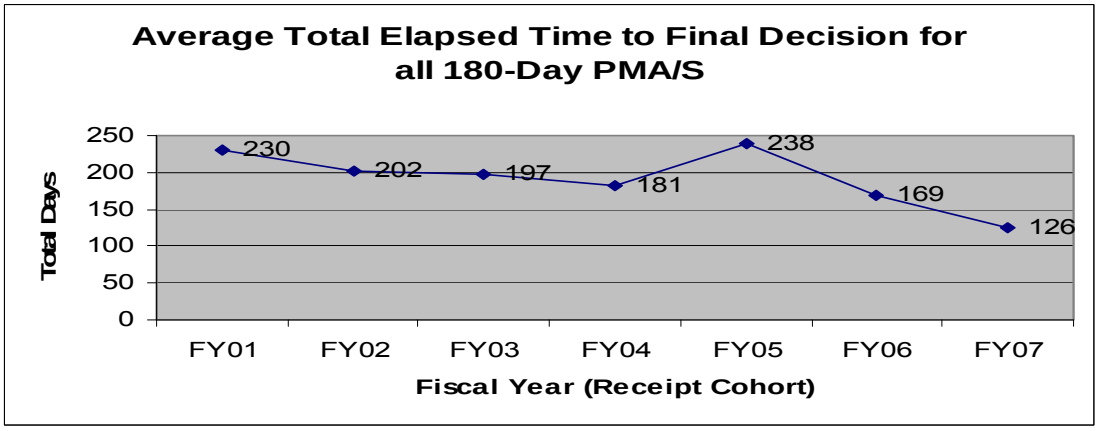
Figure 3: Average Total FDA Days from Receipt to Final Decision for all 180-day PMA Supplements –



As shown in Figure 3, the average ODE review time from receipt to final decision, one that closes a file (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 07 receipt cohort, the average ODE review time was 95 days, down from 109 days in FY 06.

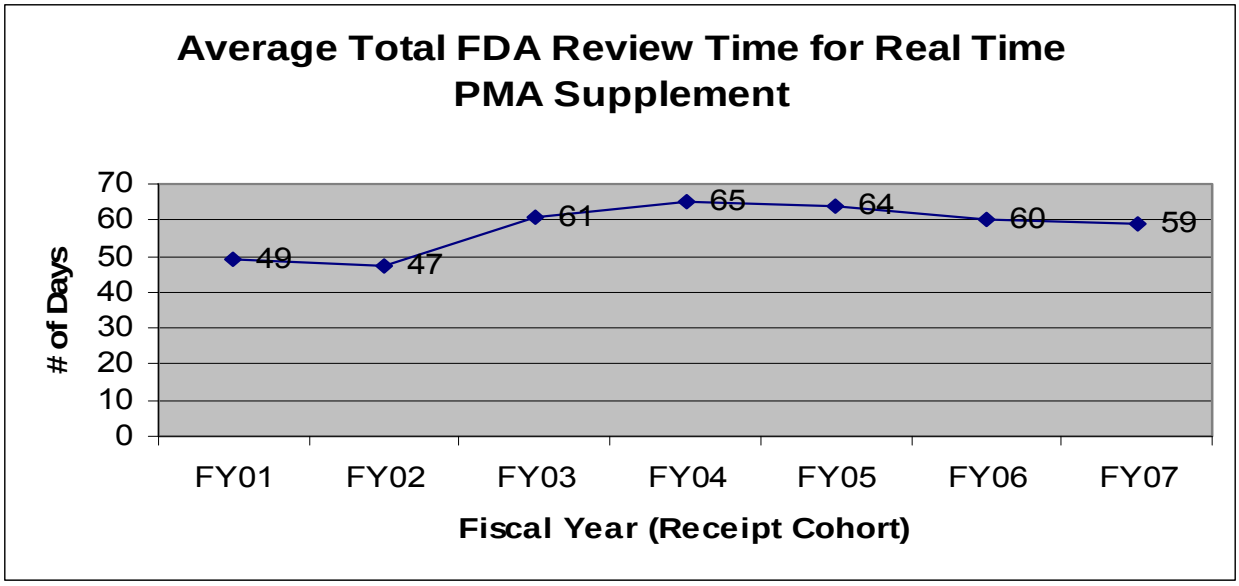
Similarly, there has been significant improvement in the average total elapsed time for 180-day PMA supplements since FY 05. For the FY 07 receipt cohort, the total time was 126 days, down from 169 days in for the FY 06 receipt cohort (see Figure 4).

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



Since FY 04, 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 between 59 and 65 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, 182 real-time supplements were received as compared to 256 received in FY 07, an increase of 41%.

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



- Product Development Protocols (PDPs)

No original PDPs were approved in FY 07. One routine PDP supplement and 2 Real-Time PDP Supplements, 2 special supplements and 18 30-day/135-day 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 declined since MDUFMA. Only data through FY 06 is being presented because FY 07 is incomplete.

Figure 6: Average FDA Time From Receipt To Final Decision

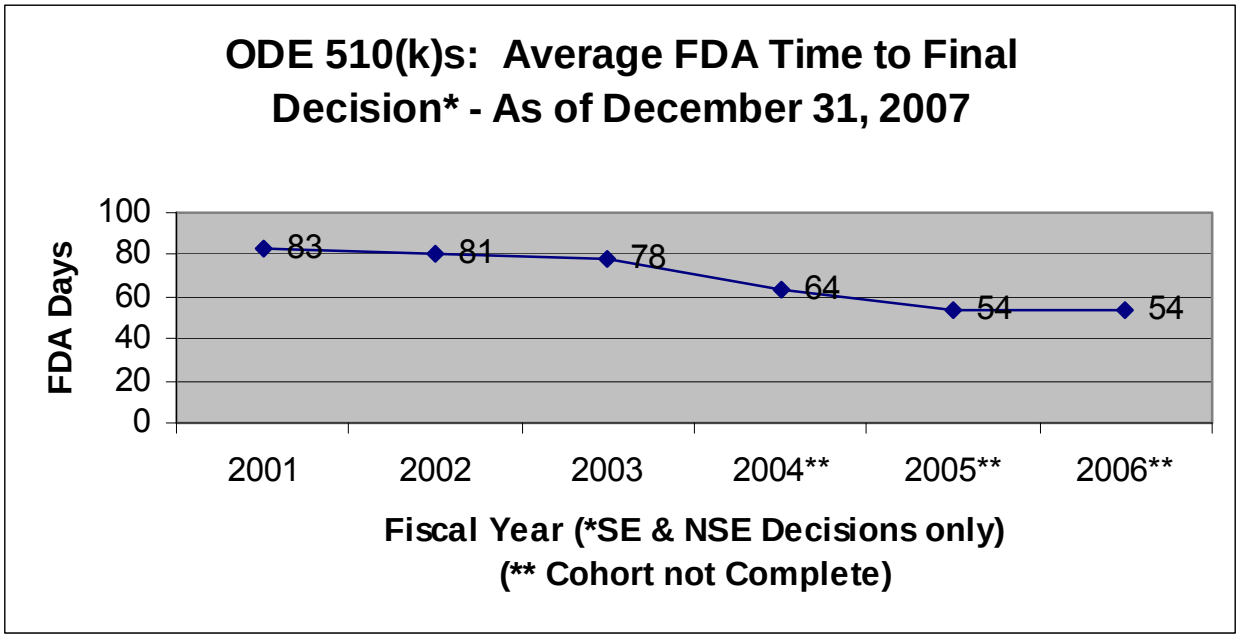
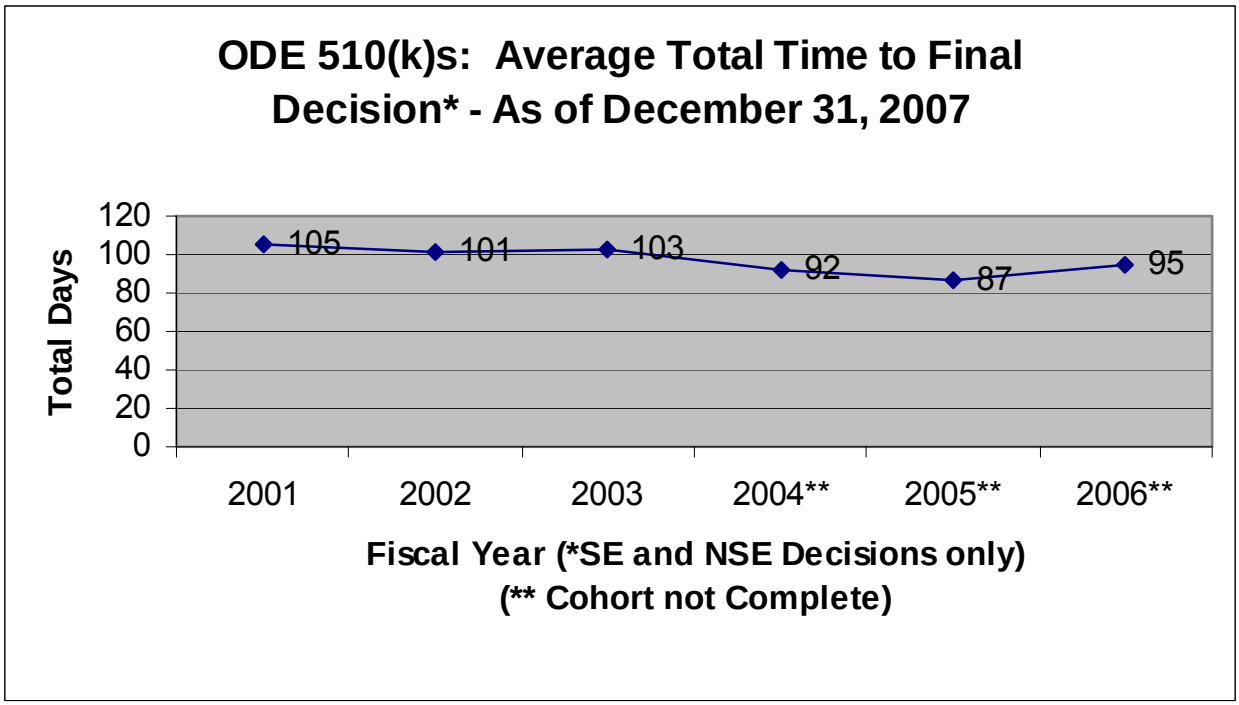


Figure 7: Average Total Elapsed Time From Receipt To Final Decision



- Third-Party Review of 510(k)s

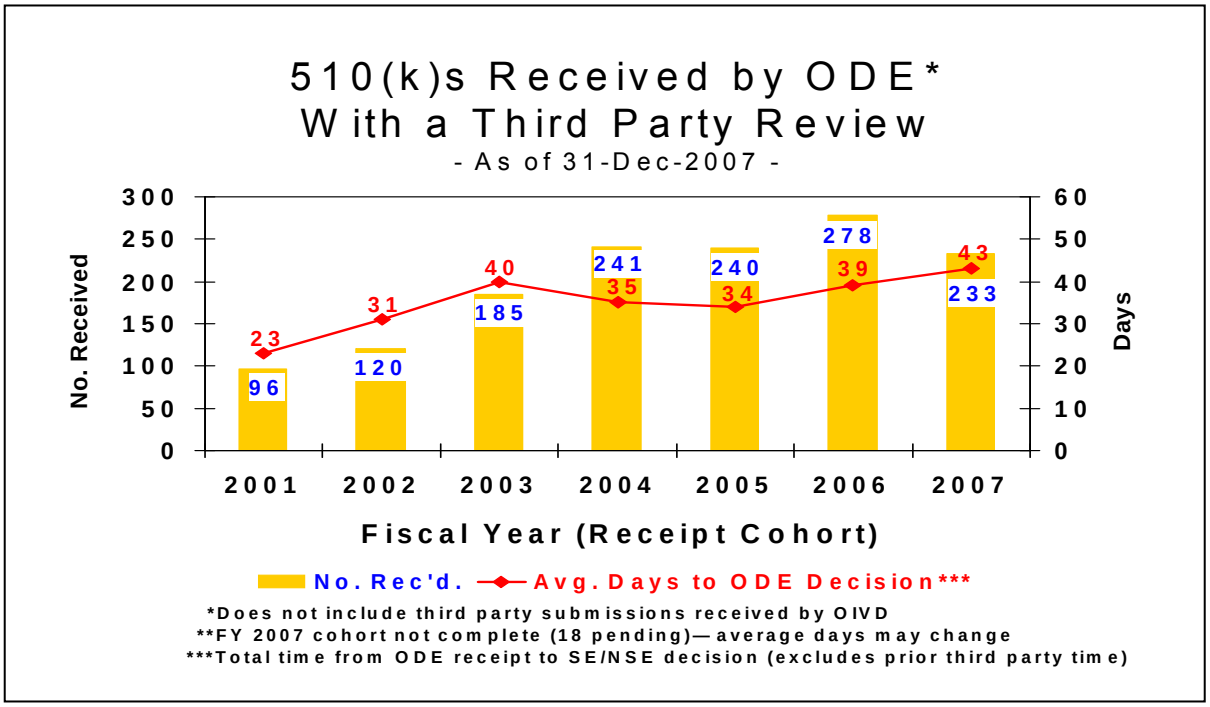
During FY 07, ODE received 233 510(k)s reviewed by third party organizations under the Accredited Persons provisions (Section 523) of the Federal Food, Drug, and Cosmetic Act. This was a 16 percent decrease from the 278 submissions received in 2006. ODE made final decisions on 230 "third party" 510(k)s in FY 07, a 13 percent decrease from the 264 final decisions in FY 06. As shown in Figure 8, the average total days from the time ODE received a 510(k) with a third party's review to the time ODE issued the final decision to the 510(k) holder was 43 days in FY 07, slightly higher than in FY 06.

On September 27, 2007, the President signed the Food and Drug Administration Amendments Act of 2007. The act includes a provision extending authority for third party review of 510(k)s through the end of fiscal year 2012. The existing statutory authority was due to expire at the end of FY 07.

CDRH continued to take steps during FY 06 and FY 07 to improve the quality and consistency of third party reviews and facilitate ODE's and OIVD's timely action on these submissions. CDRH conducted telephone conferences with all third parties in March, June, and November 2006 and March 2007 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*



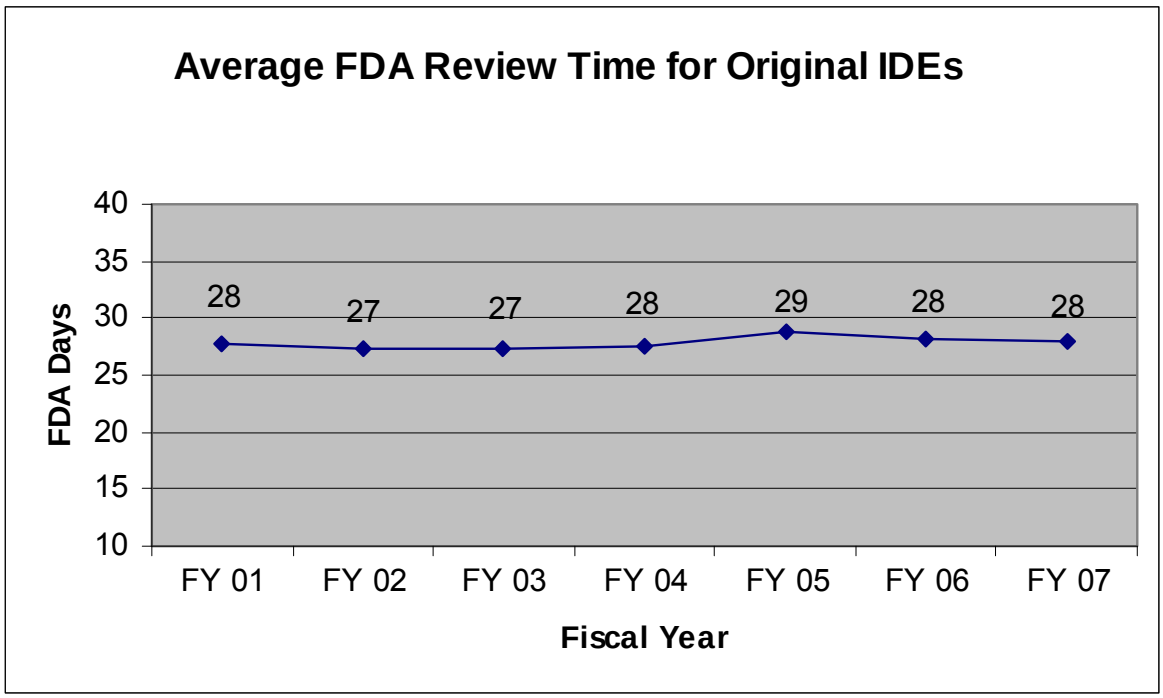
- Humanitarian Device Exemption (HDE) Applications

ODE received 6 original HDEs in FY 07. All were still under review at the end of FY 07. Two HDEs were approved in FY 07.

- Investigational Device Exemptions (IDE) Applications

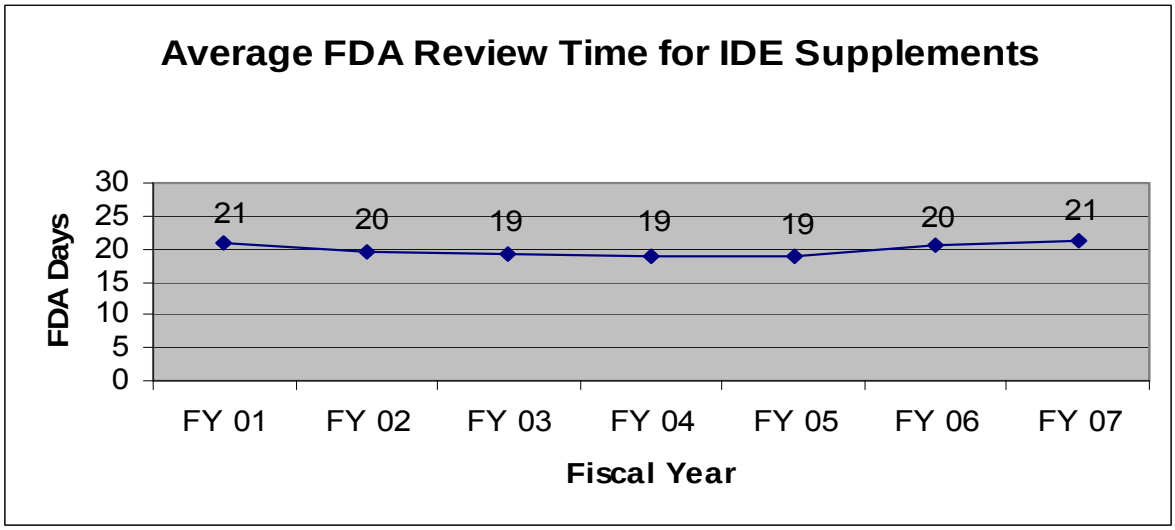
In FY 07, ODE received 211 original IDEs. There were 214 decisions made on original IDEs. Ninety-nine percent of all original IDE decisions were issued within 30 days in FY 06. The average review time was 28 days.

Figure 9: Average FDA Review Time for Original IDEs



In FY 07, 99% of the IDE supplements received were reviewed within the 30-day statutory timeframe. The average review time for IDE supplements has remained fairly constant.

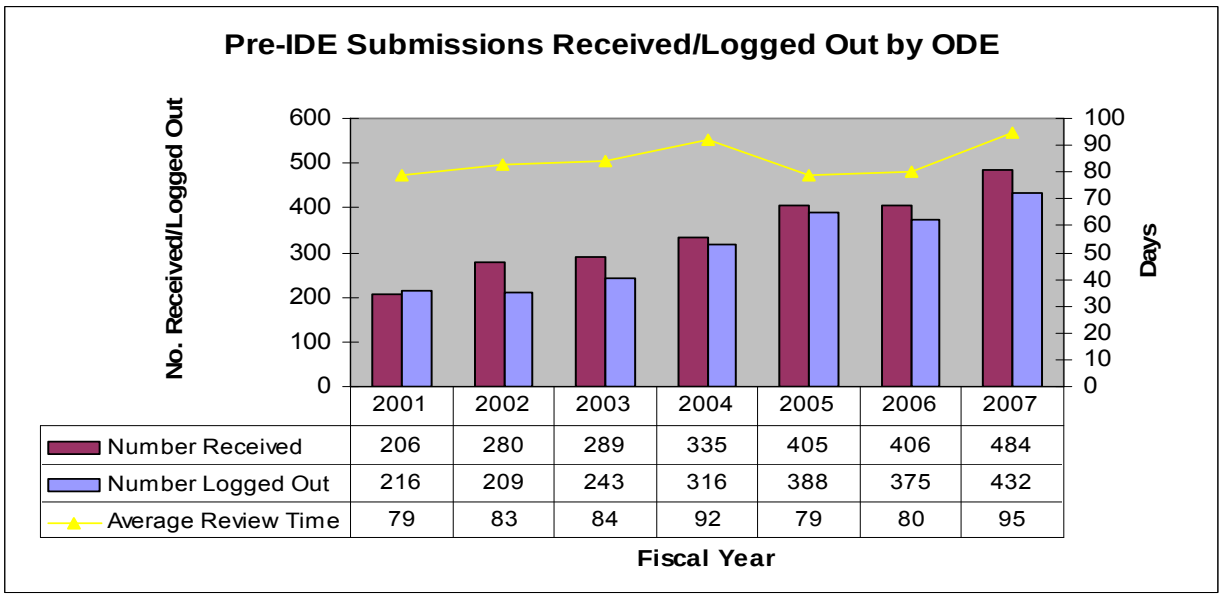
Figure 10: Average Total FDA Review Time for All IDE Supplements



- Pre-IDE Submissions

During FY 07, ODE reviewed 484 pre-IDEs. Based on these reviews, guidance for the pre-original IDE submissions were provided to the sponsors through meetings, 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. The increasing number of pre-IDE submissions is likely responsible for the increase in review times seen in FY 07.

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: http://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 1997-2007 (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 97 - FY 07

TYPE OF SUBMISSION	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
	ODE& OIVD	ODE& OIVD	ODE& OIVD	ODE& OIVD	ODE& OIVD	ODE& OIVD	ODE& OIVD	ODE Only	ODE Only	ODE Only	ODE Only
Original PMAs	48	40	36	42	53	41	31	29	28	27	27
PMA Supplements	401	421	440	474	442	533	494	424	354	594	578
Original IDEs	272	325	305	320	284	307	246	217	238	234	214
IDE Amendments	220	225	268	251	207	251	217	162	208	178	163
IDE Supplements	3,777	4,209	4,224	4,335	4,802	4,711	4,424	4,336	4,226	4,430	4,324
510(k)s	5,155	5,229	4,593	4,397	4,150	4,376	4,132	3,376	3,184	3,080	3,052
Original HDE	2	4	6	6	4	10	2	6	2	3	2
HDE Supplements	0	0	3	10	11	14	24	22	31	69	47
Total	**9,875**	**10,453**	**9,876**	**9,835**	**9,953**	**10,243**	**9,570**	**8,573**	**8,272**	**8,615**	**8,407**

- Premarket Approval Applications (PMAs)

In FY 07, ODE completed 103 PMA actions. These actions included 32 filing decisions, 30 major deficiency decisions, and 41 approval/approvable/not approvable decisions.

Of the 41 decisions made in FY 07 on original PMAs, 27 were approval orders, 7 were approvable and 7 were not approvable. Of the 27 approvals, 3 were for expedited PMAs. See Part 1 (ADVANCES IN PATIENT CARE) for a complete list of PMA approvals.

In FY 07, ODE completed 744 PMA supplement actions. These actions included 5 panel track PMA supplement filing decisions, 8 major deficiency decisions, 87 not approvable decisions, 66 approvable decisions and 578 approval decisions.

- Premarket Notifications (510(k)s)

ODE completed 3,080 510(k) actions in FY 06. These actions included 2,677 substantially equivalent decisions, 98 not substantially equivalent decisions, and 285 other decisions such as withdrawn or deleted.

ODE completed 3,052 510(k) actions in FY 07. these actions included 2,640 substantially equivalent decisions, 95 not substantially equivalent decisions, and 317 other decisions such as withdrawn or deleted.

During the FY 06, 703 Special 510(k)s received final decisions (689 were found substantially equivalent, 3 were found not substantially equivalent, and the remaining 11 had other decisions).

During the FY 07, 649 Special 510(k)s received final decisions (636 were found substantially equivalent, 1 was found not substantially equivalent, and the remaining 12 had other decisions).

One hundred thirty-one abbreviated 510(k)s received final decisions (113 substantially equivalent, 4 not substantially equivalent, and 14 other decisions) in FY 06.

One hundred thirty-four abbreviated 510(k)s received final decisions (113 substantially equivalent, 1 not substantially equivalent, and 20 other decisions) in FY 07.

ODE made final decisions on 264 “third party” 510(k)s in FY 06, and 230 in FY 07.

- 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 61% in FY 07. This represents a slight increase from the FY 06 performance level of 59%, although there is an increasing complexity of submissions and increasing number of combination product submissions.

Like original IDEs, the percentage of IDE supplements reviewed within the 30-day statutory timeframe was 99% in FY 07.

In FY 07, decisions were made on 163 amendments as follows: 67 approvals (41%); 32 disapprovals (19%); and 64 other administrative actions (39%).

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.

FY 06

- Issued an order on October 28, 2005, classifying the CardioMEMS EndoSensor System into class II 870.2855. http://www.fda.gov/cdrh/pdf5/K050939.pdf
- Issued an order on March 27, 2006, classifying The HealthCheck™ Home Test for Sense of Smell into class II 874.1600. http://www.fda.gov/cdrh/pdf5/K051653.pdf

FY 07

- Issued an order on January 30, 2007, classifying the Computerized Labor Monitoring System into class II 884.2800. http://www.fda.gov/cdrh/pdf6/K060028.pdf
- Issued an order on February 8, 2007, classifying the TephaFLEX Absorbable Suture into class II 878.4494. http://www.fda.gov/cdrh/pdf5/K052225.pdf
- Issued an order on May 8, 2007, classifying the 3M™ Respirator Model Nos. 8612F and 8670F for Use by the General Public in Public Health Medical Emergencies into class II 880.6260. http://www.fda.gov/cdrh/pdf6/K062070.pdf
- Issued an order on June 13, 2007, classifying the INRange Remote Medication Management System into class II 880.6315. http://www.fda.gov/cdrh/pdf5/K051338.pdf

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 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 or final rules under this provision in FY 06 or FY 07.

Part 6 – Program Support

Freedom of Information Requests

ODE staff received 39 FOI requests during FY 06, a decrease from 706 in the last fiscal year. During FY 06, the number of FOI requests closed was 573 compared to 637 in FY 05. The total number of FOI requests pending in ODE at the end of FY 06 is 34 compared to 422 in FY 05. In FY 07, ODE staff received 1 FOI request and closed 558 requests. The FOI requests pending in ODE at the end of FY 07 is 4. The decrease in FOI requests for FY 06 and FY 07 is due to the FOI centralization piloted in 2005-2006 and fully implemented in October 2006.

Congressional Inquiries

Staff from ODE responded to Congressional inquiries and participated in briefings on the following topics – breast implants, electromagnetic treatment devices, digital mammography, ankle implant devices, sterility issues, reuse and single-use devices. ODE also participated in hearings of Congressional committees and briefings of Congressional staff during FY 06 and FY 07. These dealt primarily with FDA's budget and MDUFMA.

Publications

During FY 06 and FY 07, ODE staff authored 46 manuscripts for publication in professional and scientific journals and delivered 300 presentations at professional, scientific and trade association meetings. See Appendix B for a bibliography of publications.

ODE Vendor Day

ODE coordinated the Ventilators Vendor Day which was held on November 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 Tyco Healthcare, Newport Medical Instruments, Inc., Draeger Medical Inc., Hamilton Medical Inc., Pulmonetic Systems, Inc., Maquet Inc., Viasys Respiratory Care, GE Healthcare, and Respironics California, Inc. participated. There were over 125 attendees. On November 15, 2006 ODE coordinated a Ventricular Assist Devices Vendor Day. Representatives from Abiomed, Inc., Jarvik Heart, Inc., Levtronix, LLC, Thoratec Corporation, Syncardia Systems, LVAD Technologies, and Ventracor, Inc. participated.

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. Forty-two employees completed the formal program in 2006 and 64 in 2007.

Recruitment

To enhance the Center's effort to increase the hiring of minorities and those with a disability, ODE participated and partnered with the Agency's EEO/Diversity Management Office to support the 2006 and the 2007 National Medical Association Career Fair, the 2006 Society for Advancement of Chicanos & Native Americans in Science Conference and Career Fair and the 2006 and 2007 Biomedical Symposium.

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

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 2006 and 2007 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.

Device Evaluation 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.

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@fda.hhs.gov
Phone: Toll Free 1-800-638-2041 or 240-276-3103 directly between the hours of 8:00 a.m. – 4:30 p.m. EST
Fax: 240-276-3101
Mail: Consumer Staff, CDRH/FDA, 1350 Piccard Drive, HFZ-210, Rockville, MD 20850

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 to the device. 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 2006 and FY 2007.

Journals, Newsletter Articles and Book Chapters

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Morris J. Review Criteria for Medical Devices that Use Antimicrobial Agents. Center for Prosthesis Infections (CPI)/Multidisciplinary Alliance Against Device Related Infections (MADRI), San Antonio, TX, August 2006.

Morris J. Oncology Image Guided Interventions: Opportunities for Collaboration. Seventh National Forum on Biomedical Imaging in Oncology, Bethesda, MD, February 2007.

Morris J. Medical Regulation. American Urogynecologic Society, Hollywood, FL, September 29, 2007.

Morris J. Adding Antimicrobial Agents to Medical Devices: A Case Study. 7th Multidisciplinary Alliance Against Device-Related Infections Center for Prosthesis Infections (CPI)/Multidisciplinary Approach for Device Related Infections (MADRI), Broomfield, CO, August 10-12, 2007, and San Antonio, TX, August 3-6, 2007.

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Nguyen T. Update on PMA Program. OCRA, Newport Beach, CA, May 2006.

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Nipper J. Premarket Submissions for Software: Special 510(k) Considerations. AdvaMed Medical Technology Software Conference, Rockville, MD, November 8, 2006.

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Nutter C. Webinar: Sterility Assurance Levels for Medical Products. Association for the Advancement of Medical Instrumentation, Arlington, VA, February 2006.

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Pena C. Regulatory Perspective on Medical Devices for Children. NIH/National Institute of Child Health & Development, Washington, DC, October 5, 2005.

Pena C. Pre-Clinical and Clinical Considerations for Neuroprosthetic Devices. Department of Defense, Marina Del Rey, CA, October 10, 2005.

Pena C. Device Therapies: Approvals Beyond MERCI. Stroke Treatment Academic Industry Roundtable Conference, Arlington, VA, May 25, 2006.

Pereira A. Snoring and Sleep Apnea. Society of Otolaryngology and Head and Neck Nurses, Baltimore, MD, March 21, 2006.

Phillips R. Panel discussion - FDA Pre-Market Regulatory Process: Applications to Technologies for Radiation Biodosimetry After a Large-Scale, Radiological Incident. CMCR Workshop, Bethesda, MD, March 27, 2006.

Phillips R. Patient Safety Measures. Imaging in Medicine Course through Johns Hopkins University, Shady Grove, MD, May 2006.

Pinto P. Challenges with Dual Drugs on DES Platforms; New Drugs and New Polymers: CDRH Perspective. CRT 2007, Washington, DC, March 7, 2007.

Pinto H. PMA Submissions Workshop - During Submission Review. AdvaMed, Washington, DC, July 26, 2007.

Pollard C. Regulatory Overview. Harvard-MIT Biomedical Enterprise Program, Cambridge, MA, November 2005.

Pollard C. Regulatory Overview on Medical Device Development. Harvard-MIT Biomedical Enterprise Program, Cambridge, MA, November 14, 2006.

Pollard C. Premarket/Postmarket. Central Atlantic States Association of Food and Drug Officials (CASA), Colonial Heights, VA, January 30, 2007.

Rhodes S. Clinical Trials of Medical Devices. US-Singapore HSE Meeting, Rockville, MD, June 13, 2007.

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Romanell L. Speaker and Moderator, 510(k) 101 Course. AdvaMed, Las Vegas, NV, February 26-27, 2007.

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Rosecrans H. 510(k) Training. AdvaMed, San Francisco, CA, July 2006.

Rosecrans H. 510(k) Process Review Considerations. MDMA, San Diego, CA September 2006.

Rosecrans H. What FDA Looks for in a Submission. IBA, Salt Lake City, UT, September 2006.

Rumm P. Avian Flu: A Global Perspective. The Collage of Physicians of Philadelphia & the Global Interdependence Center, Philadelphia, PA, September 28, 2006.

Rumm P. Risk Management in the Home and Home Health Care, FDA/University of Houston Conference on Home Health, Houston, TX, September 17-18, 2007.

Runner S. FDA Marketing Claims and the Practitioner. Second Evidence Based Dentistry Conference, Chicago, IL, November 5, 2005.

Runner S. FDA Regulatory Practices. Annual Conference of the American Association of Dental Research, Orlando, FL, March 10, 2006.

Runner S. Regulation of Dental Devices. Fourth Year Dental Students. University of Illinois, Chicago, IL, April 13, 2007.

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Samuels-Reid J. FDA and Industry Challenges: Dealing with Uncertainty. AdvaMed Health Hazard Evaluation Workshop, Section on Performing HHE and Its Impact on Field Action Decisions, Bethesda, MD, April 30, 2007.

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Saviola J. A Multi-State Outbreak of Fusarium Keratitis Linked to Contact Lens Solution Use: a Rapid Assessment of a Complex Problem. CDC Tuesday Morning Epidemiology Seminar - Guest Discussant, Atlanta, GA, June 13 2006.

Saviola J. Retinal Prostheses - Future Possibilities & Current Realities. American Academy of Optometry, Denver, CO, December 7-10, 2006.

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Shein MJ. My Device May Be Defective – When Does FDA React. 27th Annual Scientific Sessions of the Heart Rhythm Society, Boston, MA, May 2006.

Shein MJ. RFID and Active Implantable Cardiac Rhythm Management Devices Electromagnetic Compatibility. ISO RFID Working Group JTC/SC31/WG4, Arlington, VA, March 27, 2007.

Shih M and Saviola J. Collective Risk Management for a Sight-threatening Risk from the Expansion of Intraocular Gas Bubble at Various Stages of Perfluoropropane Intraocular Gas Device Life Cycle. FDA Science Forum, Washington, DC, April 20-21 2006.

Shoback B. CDRH Clinical Review of Premarket Approval Applications. Interagency Oncology Task Force (IOTF), Rockville, MD, June 2006.

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Shulman M. 510(k) Procedures and PMA Procedures. Canadian Embassy, Toronto, Ottawa and Montreal, Canada September 2006.

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Stevens T. Emerging Practices and Clinical Research Issues, American Association of Orthopaedic Surgeons, Fracture Repair Symposium, Miami, FL, April 26-28, 2007.

Swain JA. How to Design Clinical Trials: Lessons Learned. New Era Cardiac Surgery Symposium, Newport Beach, CA, January 6, 2006.

Swain JA. Historical Controls and Non-Randomized Registries in Heart Valves: FDA View. CRT, Arlington, VA, April 4, 2006.

Swain JA. Percutaneous Valves: FDA View. CRT, Arlington, VA, April 4, 2006.

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Tillman DB. The Regulatory Challenges of Combination Products. Design of Medical Devices Conference, April 2006.

Tillman DB. Medical Device Lifecycles: The Myth of 'Premarket.' AAMI Annual Conference, June 2006.

Tillman DB. Device Classification: A Brief Guide for the Perplexed. Dartmouth Drug Device Symposium, October 2006.

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Tillman DB. The Regulation of Software: An Overview, AdvaMed Medical Technology Software Conference, November 2006.

Turtil S. Let's Talk About Everything You Wanted to Know and Hot Topics: Updated 510(k) Sterility Review Guidance K90-1" Memo. International Association Healthcare Central Service Material Management (IAHCSMM), Las Vegas, NV, May 24, 2006.

Turtil S. Sterile Devices in Premarket Notification [510(k)] Submissions. CBER Educational Conference, Rockville, MD, January 16, 2007.

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Uchida T. Premarket Evaluation of DES-FDA View. CRT, Arlington, VA, April 3, 2006.

Uchida T. Adaptive Trial Design-FDA View. CRT, Arlington, VA, April 4, 2006.

Vaughan C. Percutaneous Valves: FDA View – Preclinical. CRT, Arlington, VA, April 4, 2006.

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Warburton K. Poster - Absorption of Alexidine by Contact Lenses and Lens Cases and its Effect on Disinfection Activity against *Fusarium Solani*. American Society for Microbiology general meeting, Toronto, Canada, May 21-25, 2007.

Watson A. Closing the Loop as part of a panel discussion. National Institute of Biomedical Imaging and Bioengineering, Bethesda, MD, December 19, 2005.

Watson A. Regulation of Point-of-Care (POC) Medical Devices. NIH/National Institute of Biomedical Imaging and Bioengineering, Bethesda, MD, April 12, 2006.

Watson A. Pre-filled Syringes and Combination Products: A Medical Device Perspective. Prefilled Drug Association, Bethesda, MD, October 23, 2006.

Watson A. Regulatory Context for Electronic Health Records. AdvaMed. Washington, DC, November 8, 2006.

Wood G. CDRH Advisory Panel Review. Regulatory Affairs Professional Society (RAPS) Webcast, May 23, 2007.

Yen D. Surgical robots and MRI safety from a regulatory perspective. Institute of Electrical & Electronic Engineers International Congress on Robotica & Automation, Orlando, FL, May 15, 2006.

Yen D. Points to Consider for Marketing of Computerized and Robotic Surgical Systems in the U.S. 20th International Congress on Computer Assisted Radiology & Surgery, Osaka, Japan, June 29, 2006.

Yen D. Regulating Medical Devices in the US: FDA Perspective. Surgical Grand Rounds at the Cleveland Clinic, Cleveland, OH, April 18, 2007.

Zimliki CL, Mears D, and Chenault VM. Glucose Sensing in *Psammomys Obesus* (Fat Sand Rat): Method for Converting Islets into Diabetic State. FDA Science Forum, Washington, DC, April 2006.

Zimliki C. The Physiology of Interstitial Fluids. Diabetes Technology Meeting, Atlanta, GA, November 4, 2006.

Zuckerman B. Moderator for HHS Town Hall TCT, Washington, DC, October 16, 2005.

Zuckerman B. Harmonization of Device Trials. Harmonization By Doing Symposium, Tokyo, Japan, December, 2005.

Zuckerman B. FDA and CV Development. Society of Thoracic Surgeons, Chicago, IL, January 27, 2006.

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Zuckerman B. Medical Device Development. CRT, Arlington, VA, April 4, 2006.

Zuckerman B. Percutaneous Heart Valve Development: FDA Perspective. Annual Symposium on New Interventions in Transcatheter Valve Techniques, San Francisco, CA, April 26, 2006.

Staff College Presenters and Faculty – FY 06 and FY 07

Boam, Ashley
Brown, Sheila
Ciarkowski, Art
Chakrabarti, Kish
Cotterell, Alison
Gatling, Robert
Gonzalez, Gema
Good, John
Hawthorn, Anne
Ho, Charles
Horbowyj, Roxolana
Husband, Michael
Jensen, D. Nick
Kammula, Raju
Less, Joanne
Lewis, Brian
Lin, Chiu
Mallis, Elias
Mann, Eric
Michaud, Ginette
Morris, Janine
Murphey, Sheila
Neuland, Carolyn
Nipper, Joshua
Nguyen, Thinh
Norfleet, William
Pena, Carlos
Provost, Miriam
Rechen, Eric
Rosecrans, Heather
Runner, Susan
Sacks, William
Samuels-Reid, Joy
Turtil, Steve
Watson, Anthony
Wolanski, Nicole
Zimmerman, Barbara

ODE Standards Liaison Representatives – FY 06 & FY 07

Abel, Dorothy
Adjodha, Michael
Allen, Peter
Allen, Samie
Anderson, Jodi
Baker, Karen
Beers, Everette
Berman, Michael
Berman, Sheryl
Betz, Bob
Bezabeh, Shewit
Blackwell, Angela
Bowley, Sue
Brooks, Mary
Brown, Daniel
Burdick, William
Byrd, Laura
Calogero, Don
Carey, Carole
Carstensen, Peter
Cavanaugh, Ken
Chen, Tzeng
Cheng, Jim
Choe, Melanie

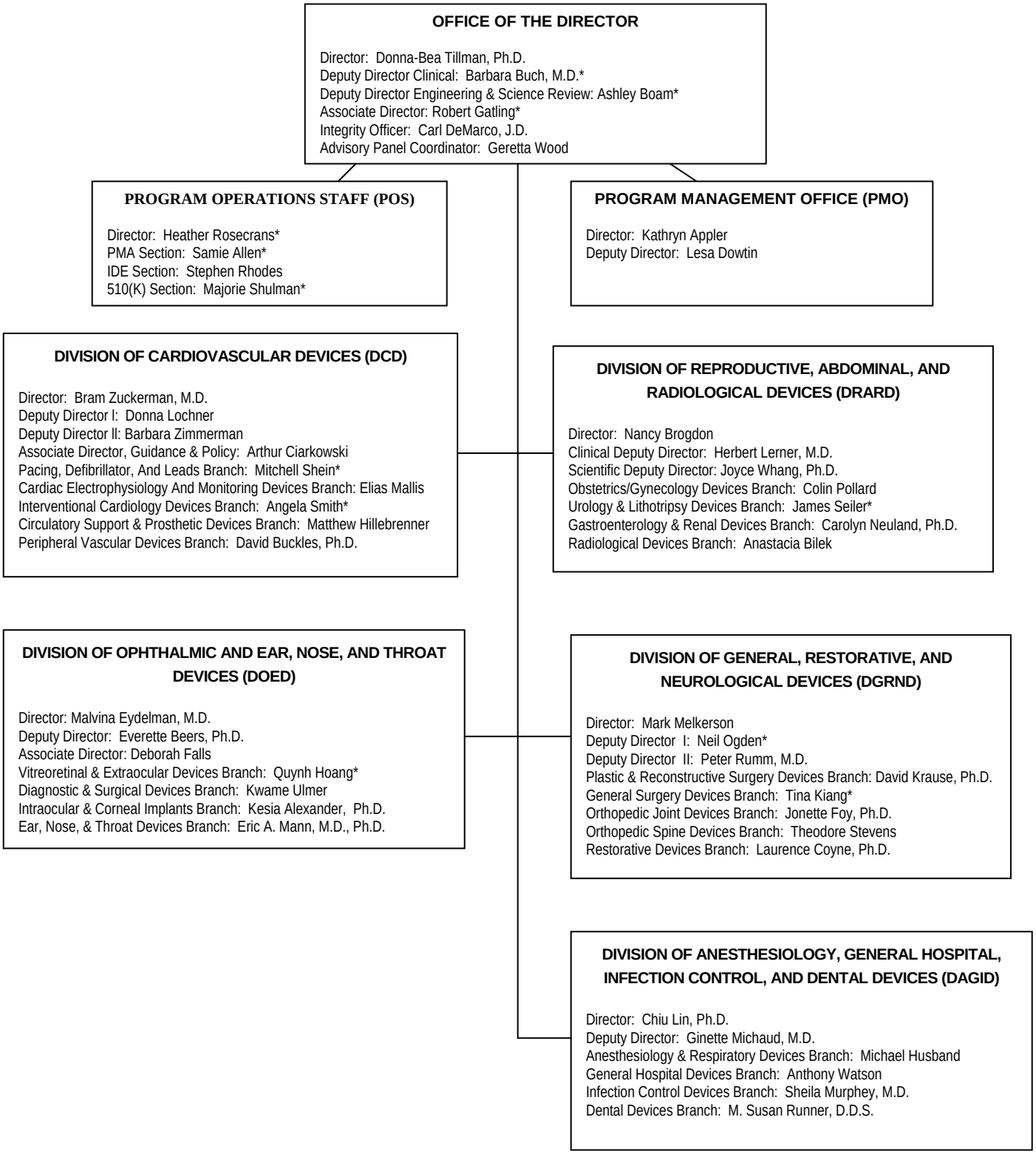
Ciarkowski, Art
Colburn, Scott
Cornelius, Mary Jo
Cunningham, Terrell
Cygnarowicz, Teresa
Daws-Kopp, Kathryn
DeLuca, Robert
Demian, Hany
Doyle, Bob
Drum, Bruce
Eydelman, Malvina
Felton, Richard
Ferriter, Ann
Fox, Pat
Foy, Jonette
Gantt, Doyle
Gonzalez, Gema
Goode, Jennifer
Goode, John
Gouge, Susan
Graham, Ann
Guay, Justin
Hinckley, Steve
Ho, Charles
Holden, John
Holt, Vivianne
Husband, Michael
Jayan, Geetha
Jensen, Nick
Kaiser, Aric
Kammula, Raju
Kane, James
Kang, S. Andrew
Kaye, Ronald
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
Michaud, Ginette
Mills, Kristin
Mulry, Kevin
Murphey, Sheila
Naveau, Irene
Nell, Diane
Nimmagadda, Venkat
Nutter, Cathy
Ogden, Neil
Panguluri, R. Kapil
Patel, Neel
Phillips, Robert
Pinto, Hina
Pollard, Collin
Rhodes, Stephen
Riley, Erin
Rios, Michelle
Ryan, Michael
Sauberman, Harry
Saviola, James
Schmidt, Jennifer
Schroeder, Marie
Shein, Mitchell
Shi, Dexiu
Shih, Ming-Chuen
Shiu, Lana
Smith, Myra
Soprey, Pandu
Tillman, Donna-Bea
Toy, Jeffrey
Turtil, Steve
Watson, Anthony
Warburton, Karen
Weitershausen, Joanna
Wentz, Catherine
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 Instructions for Submitting	http://www.fda.gov/cdrh/guidance.html
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 04/28/08



*Acting

Appendix E – ODE Staff Roster (FY 07)

Office of the Director

Boler-Bonny, Adrian
DeMarco, Carl
Gornick, MaryAnn
Hill, Ayanna
Hobbs, Cathy
Nguyen, Thinh
Provost, Miriam
Tillman, Donna-Bea
Yustein, Ron
Wood, Geretta

Program Management Office

Appler, Kathryn
Canizares, Julian
Colleli, Karen
Dowtin, Lesa
Graves, Tonnetta
Hackey, Elise (Potsy)
Jaeger, Jeff
Phillips, Shirley
Wedlock, Chuck
Williams, Nailah

Program Operations Staff

Allen, Samie
Beverly, Pat
Brown, Sheila
Byrd, Laura
Cassis, Domini
Demian-Rumer, Cindy
Fisher, Lisa
Garcia, Diane
Gatling, Robert
Harvey, Elisa
Hawthorn, Anne
Lenardo, Brian•
Lyons-Drager, Linda
Melvin, Marsha
Rechen, Eric
Rhodes, Stephen
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#
Aguel, Fernando
Anderson, Evan∴
Anderson, Nels
Barnett, Michael∴
Boam, Ashley
Bowley, Susan
Brockman, Randy
Brown, Michele
Buckles, David
Buckley, Donna
Burke, Ryan
Carey, Carole*
Cavanaugh, Kenneth
Chan, David
Chandeysson, Paul
Chen, Eric
Cheng, Jim
Ciarkowski, Art
Eloff, Ben
Enyinna, Kachi
Ewing, Lesley*
Farb, Andrew
Faris, Owen
Fellman, Mark
Fiorentino, Robert
Fleischer, Dina
Foy, Keith
Fronczak, Katie
Gantt, Doyle

Garma, Pharoah
Goode, Jennifer
Hagler, Donald∴
Hallab, Annie
Hampshire, Victoria
Higginson, Katie•
Hillebrenner, Elizabeth
Hillebrenner, Matthew
Ho, Charles
Holt, Vivianne
Hottenstein, Omar
Huynh, Ann
Hwang, Shang
Jones, Edwena
Kaiser, Suzanne
Kennell, Lisa
Kroen, Marian
Krueger, Matt
Kurtzman, Steve
Lacy, Frank
Lappalainen, Sharon#
Lee, James
Lemperle, Bette
Letzing, Bill
Leville, Lisa
Lewis, Brian
Lochner, Donna
Mallis, Elias
McKee, Jarad
Mezu-Nwaba, Nina
Moyal, Albert
Moynahan, Megan
Muni, Neal∴
Nell, Diane
Nguyen, Quynh Nhu
O'Callahan, Kathyrn∴
Patel, Sonna
Peters, Kimberly
Pinto, Hina
Piotrowski, Adam
Ralston, Luke
Ramdat, Deb
Reilly, Sabina
Richards, Robert•
Riemenschneider, Bill
Ryan, Tara
Samadnejad, Sami
Sapirstein, John∴
Sapirstein, Wolf
Selzman, Kimberly∴
Shein, Mitchell
Shoemaker, Linda
Smallwood, Senora
Smith, Angela
Swain, Julie∴
Swink, James∴
Terry, Doris
Tovar-Calderon, Oscar#
Uchida, Takahiro∴
Ulmer, Kwame
Usher, Wil
Vaughan, Carolyn
Wentz, Catherine
Zimmerman, Barbara
Zuckerman, Bram

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

Adjodha, Michael
Betz, Robert
Blackwell, Angela
Blount, Sharon
Brooks, Mary##
Browne, Myra
Burdick, William
Chapman, Richard
Choe, Melonie
Colburn, Scott##
Cox, Ann#
Cunningham, Terrell
De, Sugato
Gantt, Gail
Graham, Ann
Guay, Justin
Harkavy, Lorraine
Hsu, Wenchi•
Husband, Michael
Jayan, Geetha
Kern, Charles
Lin, Chiu
Love, Kimberly##

Maloney, William
Mayhall, Elaine
Michaud, Ginette
Mulry, Kevin
Murphey, Sheila
Norfleet, William∴
O'Connell, Linh
Panguluri, Ramesh
Patel, Neel
Pham, To-Oanh
Rios, Michelle##
Rogers, Kristin
Runner, Susan
Ryan, Michael
Samuels-Reid, Joy
Sauberman, Harry
Schmidt, Jennifer
Shiu, Lana
Soprey, Pandu
Spooner, Katherine
Steen, Andrew∴
Stevens, Alan##
Syed, Sajjad
Taylor, Chirelle
Turtil, Steve
Watson, Anthony
Wilson, India
Zimliki, Charles

Division of General, Restorative, and Neurological Devices

Allen, Peter
Anderson, Jodi
Arepalli, Sambasiva
Ashar, Binita
Baird, Clinton∴
Basu, Sankar
Bechtold, Stephanie
Berkowitz, David
Berne, Bernard
Bowsher, Kristen##
Buch, Barbara
Burney, Kareem##
Butler, Arlene
Chen, Long
Chowdhury, Atiq
Copeland, Randolph
Costello, Ann
Courtney, Michael
Coyne, Laurence
Dalal, Rakhi
Dang, Jiyoung
Dawisha, Sahar
De Del Castillo, Sergio
Demian, Hany##
Doll, Sara∴
Durfor, Charles
Einberg, Elmar
Eudy, Michael
Felten, Richard
Ferriter, Ann
Fogarty, Pauline
Foy, Jonette
Francis, Jacqueline##
Frank, Elizabeth
Gantenberg, Julie*
Gavini, Deepa
Getzoff, Natalie
Goode, John
Graham, Jove*
Hack, Christopher
Hammond, Della##
Hanafi, Nada
Herzog, Calley
Hill, Genevieve
Hinckley, Steve
Hoffmann, Michael
Horbowyj, Roxi
Hudson, Peter
Janda, Michael
Jean, Ronald
Johnson, Tiffany*
Jose, Jismi
Kaiser, Aric
Ki, Tajanay##
Krause, David
Kuekan, Brett•
Lee, Kyung
Li, Khan∴
Lim, Lisa
Lyons, John*
Malli, Suzanne

Marjenin, Timothy•
Martin, Tynetta
Mattamal, George
Matthews, Tonya
Melkerson, Mark
Mills, Kristin
Mishra, Nirmal
Ngaha, George
Ogden, Neil
Owens, Michael
Parvinian, Bahram
Peck, Jonathan
Phillips, Mary Ellen
Pinder, Bryan∴
Popovic, Neven
Rhodes, Hollace
Rumm, Peter
Schroeder, Marie
Scudiero, Janet
Shepherd, Janet
Shure, Deborah∴
Sloan, Nadine
Stevens, Theodore
Sturniolo, Michael
Sung, Pei
Vega, Dora
Virani, Jitendra
Warfield, Diane
Weiblinger, Richard
Whited, Bryce
Yen, Dwight

Division of Ophthalmic and Ear, Nose, and Throat Devices

Alexander, Kesia
Austin-Hansberry, Lori
Baker, Karen
Beers, Everette
Berman, Sheryl
Beylin, Alex
Brown-Smith, Kimberly∴
Buchen, Shelley*
Buttemere, Clay
Callaway, Jan##
Calogero, Don
Clupper, Daniel
Cohen, Ethan#
Cunningham, Bradley##
Cygnarowicz, Teresa##
Dahr, Sami*
Doddapaneni, Sasi∴
Drum, Bruce
Eydelman, Malvina
Falls, Deborah
Ghosh, Molly
Hampton, Denise
Hilmantel, Gene
Hutter, Joseph
Jones, Susanna
Kane, James
Kaufman, Daryl##
Khan, Anjum
Kiang, Tina
Kramm, Lee
Krawczyk, Claudine*
Lepri, Bernard##
Leslie, Sharmeka
Malshet, Vasant
Mann, Eric
Moore, Shirley
Nair, Sushma*
Nandkumar, Srinivas
Nicholas, Marsha
Ortega, Maritze
Peng, Shu-Chen
Robboy, Marc
Rorer, Eva
Saviola, James
Selfon, Eric
Shi, Dexiu
Shih, Ming-Chuen
Smith, Myra
Storer, Patricia
Toy, Jeffrey
Ulmer, Kwame
Virmani, Mridulika
Warburton, Karen
Yang, Andrew

Division of Reproductive, Abdominal, and Radiological Devices

Allen, Cheryl
Andrews, Sharon
Bailey, Michael
Baxley, John
Beardsley, Christina∴
Bell, Glenn
Bilek, Anastacia
Blyskun, Elaine
Brogdon, Nancy
Byrne, Michelle
Carr, Linda
Chakrabarti, Kish
Chan, Dulciana#
Chen, John
Cooper, Jeffrey
Cornelius, Mary Jo##
Corrado, Julia
Cotterell, Alison
Czerska, Ewa
Dart, Linda
Daws-Kopp, Kathryn
DeLuca, Robert
Eba, FeLisa
Fu, Xin
Giere, Joseph∴
Gonzalez, Gema
Hardy, Paul##
Heaton, Thomas*
Hefner, Lauren
Herrera, Hector
Hossain, M. Ashraf
Howell, Kimberly
Jevtich, Milorad
Kammula, Raju
Kang, S. Andrew
Kuchinski, Michael
Lauritsen, Kristina
Law, Michelle
Lerner, Herbert
Mackey, Cheryl
McBryde, Kevin∴
Mickal, Megan
Mitchell, Diane
Morris, Janine
Myers, Charles
Neuland, Carolyn
Nicholas, Julian∴
Nimmagadda, Venkat Rao
Nipper, Joshua
Nutter, Cathy
O'Brien, Mary Beth##
Oliver, Karen
Olvey, Kathleen
Paquerault, Sophie#
Phillips, Robert#
Pollard, Colin
Price, Veronica
Rajan, Sunder
Rubendall, Rita
Ruiz-Zacharek, Claudia*
Sandler, Howard▫
Segerson, Dave
Seiler, Jim
Smith, Robert
Stephenson, Rebecca
Straughn, Kellie
Vorvolakos, Katherine#
Wallner, Paul*
Weinel, Pamela
Wersto, Nancy##
Whang, Joyce
Williams, Richard
Zaremba, Loren

* Contractor
Collaborative Reviewer
\# Joint Appointment
▫ Sabbatical
• Summer Student/Co-Op
∴MDFP Hire