

CDRH FY 2004 Annual Report

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

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Opening Remarks from the Center Director

Dear Reader,

I'm pleased to issue the annual report for FDA's Center for Devices and Radiological Health covering Fiscal Year 2004. This was my first full year as Center Director, and it's given me a deep appreciation of the enormous responsibilities that go with the job. More importantly, I've gained an even deeper appreciation of the key qualities that make this Center outstanding: the dedication and drive of the people who work here.

It was largely those qualities that enabled us to meet the premarket MDUFMA milestones. To be sure, what you'll read in this report are tables and charts that summarize the number of submissions received, the number approved, found SE'd, or NSE'd. But what you won't see—because we lack the tools to capture and showcase this information—is the esprit de corps and teamwork that made it possible to achieve these milestones. Let me relate just one example. I recall the pressure the Center faced at the end of September to meet the October 1 deadline for taking action on the Supplement Validation Submissions submitted by single use device reproprocessors. It was well past the traditional quitting time, but I saw people working into the evening hours to complete their reviews, making calls to their lab counterparts to confirm facts or checking with postmarket colleagues to get their input. As I watched this pace continue unabated into the weekend, it was clear to me that these folks were motivated by a strong sense of responsibility and a commitment to public health. And as I've seen all year, that spirit is shared all across the Center.

Another key that led to a very successful FY 04 was the fact that staff reached across divisions and offices to accomplish their work. Review teams included premarket and postmarket members. Numerous meetings, countless emails back and forth, and creation of e-rooms were all vehicles used to discuss settle points of disagreement, and develop Center consensus. This spirit of working together is exemplified in the cooperative pilot project between our postmarket epidemiologists and our PMA reviewers, now in its second year. Over the course of this year, epidemiologists have been working side by side with premarket application reviewers in all aspects of the review process—developing postmarket follow-up plans, designing post-approval studies, and following and monitoring the progress of already initiated PMA post-approval studies.

In keeping with the FDA-wide emphasis on risk-based regulation, this year we began using criteria that allowed us to focus our limited field resources on inspecting medical devices and manufacturers that present the greatest risk to public health. We made a

similar effort in our bioresearch monitoring (BIMO) program, where we began performing BIMO inspections of clinical trials involving pediatric and physically challenged patients during the research phase of an investigational device, rather than after submission of a PMA. This early intervention helps prevent improper research from harming patients and interfering with the advancement of medical technology.

It's important to remember that the second "M" in MDUFMA stands for "Modernization," which means taking a serious look at our infrastructure. User fees allowed us to begin doing that, giving us the opportunity to make a deposit—albeit a small one—into updating our IT systems. For example, we deployed the initial version of a premarket review tracking system that will help us manage submissions, and we launched a pilot program that will enable manufacturers to complete a 510(k) original submission electronically. This is the kind of investment of resources that won't necessarily reap dividends in the current fiscal year, but will begin paying off in future years. Without MDUFMA funds, we wouldn't have been able to launch these projects.

On the postmarket front, we expanded the east coast and mid-west regional coverage of MedSun, our medical facility adverse event reporting system, by recruiting 180 new facilities, bringing the national number of reporting hospitals to 299. We also launched a pilot project called "LabSun," and began collecting very useful pathology and in vitro diagnostics test reports from laboratories in the reporting hospitals.

We completed a 2-year review of CDRH's Radiological Health Program and concluded that unnecessary population exposure to radiation comes largely from medical sources, and that the problem stems mainly from how medical radiation equipment is used, rather than equipment-related problems. To better address these findings, we have refocused our limited radiological health resources towards user and public education.

Science remains a priority for the Center. One example of how our scientists help move technology from bench to bedside can be found in the area of computer-aided diagnosis. Our scientists played a pivotal role in the approval of the first computer-aided diagnosis (CAD) system for detecting lung nodules on CT scans, one of the most significant medical devices approved this year. Anticipating this cutting-edge technology, they worked on developing the statistical methodology needed to demonstrate the effectiveness of the device, which facilitated its evaluation and approval.

Finally, we're playing an important part in the FDA's efforts to deal with national security. Our emergency response plan was updated; we have in place a process to identify and manage medical device shortages during public health emergencies; our scientists, working with FAA, studied the effect of metal detectors on medical devices; and, for the first time, an anthrax test is available for use in state and private laboratories.

What I've provided here is just a brief overview of what CDRH has been doing over the past year. I encourage you to read the full report to get a more complete picture of what we've accomplished. I'm proud of those accomplishments, and grateful to everyone in CDRH for helping to make them possible.

A handwritten signature in black ink, appearing to read "Dan Schultz". The signature is fluid and cursive, with a large initial "D" and "S".

Daniel G. Schultz, M.D.
Director, Center for Devices and
Radiological Health

Center for Devices and Radiological Health

The Center for Devices and Radiological Health (CDRH) is part of the U.S. Food and Drug Administration (FDA). CDRH promotes and protects the health of the public by ensuring the safety and effectiveness of medical devices as authorized by the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act and helps reduce unnecessary exposure to radiation from medical, occupational, and consumer products as authorized by the Radiation Control for Health and Safety Act of 1968. We achieve our mission by ensuring the health of the public throughout the "Total Product Life Cycle (TPLC)" of the products we regulate. Our TPLC vision embraces our commitment to focusing on all the stages in a product's life, from development and design through obsolescence.

CDRH consists of six [Offices](#):

- Office of the Center Director (OCD)
- [Office of Communication, Education and Radiation Programs](#) (OCER)
- [Office of Compliance](#) (OC)
- [Office of Device Evaluation](#) (ODE)
- [Office of In Vitro Diagnostic Devices Evaluation and Safety](#) (OIVD)
- Office of Management Operations (OMO)
- [Office of Science and Engineering Laboratories](#) (OSEL)
- [Office of Surveillance and Biometrics](#) (OSB)

Additional information about CDRH is available by calling 1-888-INFO-FDA or by visiting the CDRH website at www.FDA.Gov/CDRH.

New Leadership

[Daniel G. Schultz, M.D.](#)

Director, Center for Devices and Radiological Health

In July, acting FDA Commissioner Dr. Lester M. Crawford named Daniel G. Schultz, M.D., Director of the Center for Devices and Radiological Health (CDRH). Dr. Schultz joined FDA in 1994 as a medical officer in the General Surgery Branch of CDRH. During his career at FDA Dr. Schultz has been selected to various positions, including, chief medical officer in CDRH's Division of Reproductive, Abdominal, and Radiological Devices (DRARD) in the Office of Device Evaluation (ODE), DRARD Division Director, ODE Deputy Director, and ODE Director.

A native of New York City, Dr. Schultz graduated from the City College of New York with a B.A. in political science. He received an M.D. from the University of Pittsburgh in 1974 and completed a combined internship in pediatrics and medicine at the University of New

Mexico. In 1975, Dr. Schultz joined the Commissioned Corps of the U.S. Public Health Service. He served a three-year assignment as a general medical officer and clinical director of the Tuba City Indian Hospital on the Navajo reservation in Arizona and later completed a general surgical residency at the Public Health Service Hospital in San Francisco, California. In 1981, Dr. Schultz moved to Denver, where he did a fellowship in pediatric surgery and completed his general surgery training. Dr. Schultz is board certified in general surgery and family practice and is a Fellow of the American College of Surgeons.

Lynne Rice

Director, Office of Communication, Education and Radiation Programs

Ms. Lynne Rice was selected to serve as the Director of the Office of Communication, Education, and Radiation Programs (OCER) in March 2004. Ms. Rice has been employed by the U.S. Food and Drug Administration for over 24 years. She began her FDA career with the Bureau of Medical Devices, Office of Compliance in 1979, and joined the Division of Small Manufacturers Assistance (DSMA) in the Office of Training and Assistance in 1989 as a consumer safety officer. In 1996, Ms. Rice became the Deputy Division Director of DSMA, where she was responsible for directing staffing, budget, external affairs, consumer outreach, international activities, industry analysis, guidance development, oversight of Division websites and developing educational programs for newly proposed and final medical device regulations. In June 2002, Ms. Rice was selected as Deputy Office Director of the Office of Health and Industry Programs, OCER's predecessor. Her leadership skills and outstanding ability to communicate CDRH's message to our stakeholders as Deputy Office Director made her a natural selection for her role as Director of OCER.

In 1980, Ms. Rice received a B.A. in sociology and a B.S. in biology from Mt. St. Mary's College, in Emmittsburg, Maryland. She is also a graduate of the Federal Executive Institute Leadership in a Democratic Society Program.

Dr. Donna-Bea Tillman, Ph.D.

Director, Office of Device Evaluation

In September, Dr. Donna-Bea Tillman became the Office of Device Evaluation Director. Dr. Tillman began her career in government with the Consumer Product Safety Commission, where she spent 3 years working to develop consensus standards for consumer products. In 1994, she joined ODE as a reviewer in the OB/Gyn Devices Branch, and in 1997, she was selected as the Branch Chief of DCRD's Pacing and Neurological Devices Branch. In the fall of 2000, Dr. Tillman did a six-month fellowship on Capitol Hill in the Office of Congresswoman Louise Slaughter, where she was involved in legislation involving Medicare prescription drug reform and protection of private genetic information. Shortly after her return to FDA in 2001, Dr. Tillman was selected Deputy Director for the Division of Cardiovascular and Respiratory Devices of ODE and later Deputy Director of ODE for Technology and Review Policy. She provided a template for TPLC/MDUFMA recruitment and hiring teams, which has resulted in a tremendous infusion of new talent, not only for ODE but for all of CDRH.

Dr. Tillman earned a B.S.E. in Engineering from Tulane University in 1985, and a Ph.D. in Biomedical Engineering from the Johns Hopkins University in 1992.

Part 1. Technology and Innovation (CDRH Strategic Goal: Public Health Impact)

Bringing New Products to the Market

In FY 04 CDRH approved or cleared thousands of devices used to diagnose or treat a wide variety of medical conditions, including:

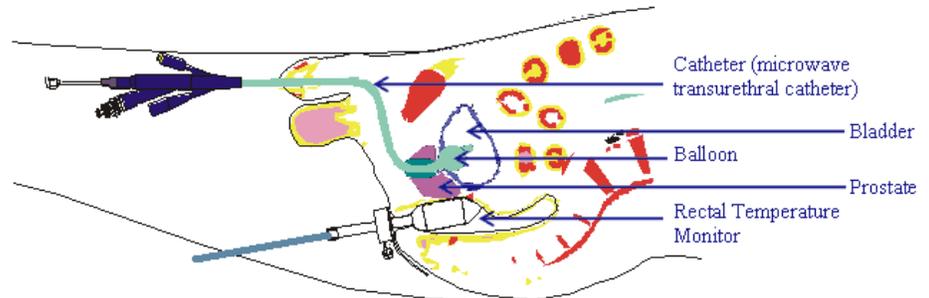
- **Philips HeartStart Home OTC Defibrillator** - the first over-the-counter AED cleared by FDA for lay users.
- **ImageChecker® CT CAD Software System** - the first image analysis system designed to help radiologists review computed tomography (CT) images of the chest to aid in the detection of solid nodules in the lungs.
- **DeBakey VAD® Child** - the first miniaturized heart pump (ventricular assist device) approved for use in children aged 5 to 16 who are awaiting a heart transplant.
- **QuickELISA Anthrax-Pa Kit** - the first rapid serum antibody test for anthrax.
- **NeoGram Amino Acids and Acylcarnitine Tandem Mass Spectrometry Kit** - the first pediatric device for neonatal screening for general inborn errors of amino acid metabolism.
- **CellSearch™ Epithelial Cell Kit / CellSpotter™ Analyzer** - a new biomarker for determining survival in patients being treated for end stage breast cancer.
- **OraQuick® Advance Rapid HIV-1/2 Antibody Test** - the first point of care test for this antibody and the first test suitable for general field use.
- **CEDIA® Sirolimus Assay** - the first assay for a new immunosuppressive drug in over a decade.
- **Ventana® Medical Systems' PATHWAY Anti-c-KIT (9.7) Primary Antibody** - the first IHC marker to assist in diagnosis and treatment selection in patients with a rare GI tumor.

Part 1. Technology and Innovation

These devices are examples of technology for new indications approved or cleared during this past fiscal year that have a particular impact on patient care.

Benign Prostatic Hyperplasia

Prolieve™ - Approved February 2004, Prolieve™, manufactured by Celsion Corporation, is a transurethral microwave therapy (thermodilatation) system that uses microwave energy to treat Benign Prostatic Hyperplasia (BPH), a non-cancerous



enlargement of the prostate gland that commonly affects men over the age of 50. The Prolieve™ device is intended to treat the symptoms of BPH by compressing and heating prostatic tissue that may be blocking the flow of urine. Prolieve™ consists of a permanent instrument and a single-use procedure kit. Prolieve™ delivers microwave energy to the prostate with simultaneous balloon-administered compression (thermodilatation) for 45 minutes. The device provides a non-surgical, minimally invasive treatment of symptomatic BPH in men with a prostate volume of 20 to 80 grams, and in whom drug therapy (e.g., Proscar®) is typically indicated. Prolieve™ may reduce the primary symptoms of BPH that include incomplete bladder emptying, frequent urination, urinary intermittency, urgency, a weak stream, straining to urinate and excessive urination at night (nocturia). Prolieve™ has also been demonstrated to improve peak flow rate, quality of life, post-residual volume, and other disorders associated with urination.

Bone Graft

INFUSE® Bone Graft - Approved April 2004, the INFUSE® Bone Graft, by Wyeth Pharmaceuticals, is intended to be used along with an intermedullary nail (IM nail) to help heal bone fractures of the lower leg or tibia. The INFUSE® device consists of two parts: a genetically-engineered human protein (rhBMP-2) to stimulate bone healing, and an absorbable collagen sponge made from cow (bovine) collagen that is soaked with protein. A metal rod, called an intermedullary nail or IM nail, is surgically implanted inside the tibia bone to stabilize the fracture. The INFUSE® device is implanted at the fracture site to help the bone heal. The device is intended to be used along with internal stabilization (an IM nail) to help heal a fresh, open fracture of the tibia.

Breast Cancer

CellSearch™ Epithelial Cell Kit / CellSpotter™ Analyzer - The CellSearch™ Epithelial Cell Kit / CellSpotter™ Analyzer by Veridex, LLC, a Johnson and Johnson company, was cleared for marketing in January 2004. The CellSearch™ Epithelial Cell Kit / CellSpotter™ Analyzer is intended to be used on breast cancer



Part 1. Technology and Innovation

patients to monitor and to help determine the effectiveness of the cancer treatment. The CellSearch™ Epithelial Cell Kit helps the pathologist identify Circulating Tumor Cells (CTC) in the blood. The CTC are then counted by the pathologist with the aid of the CellSpotter™ Analyzer. The more CTC there are in the blood, the less effective the cancer treatment is believed to be.

Cardioveters, Defibrillators and Pacing Systems

Philips HeartStart Home OTC Defibrillator - The HeartStart Home Defibrillator, manufactured by Philips Medical Systems, is a small, lightweight [Automatic External Defibrillator \(AED\)](#) specifically designed for use without a prescription. Approved September 2004, the device shocks the heart to restore rhythm in patients with life threatening cardiac rhythms. The HeartStart home defibrillator is cleared for use on adults or on children who are at least eight years old or older or who weigh at least 55 pounds. Special small pads are available by prescription for pediatric use. This device is the first over-the-counter AED cleared by FDA for lay users.



Guidant Cardiac Resynchronization Therapy Defibrillators (COMPANION trial) - The Guidant CONTAK CD, CONTAK CD2, RENEWAL, and RENEWAL 3, manufactured by Guidant Corporation, are [Implantable Cardioverter Defibrillators \(ICDs\)](#) that also deliver [Cardiac Resynchronization Therapy \(CRT\)](#). These ICDs received approval in September 2004. These devices use small electrical impulses to coordinate heart rhythm and improve blood pumping ability in certain patients with moderate to severe heart failure. A Guidant CRT-D delivers CRT to help coordinate the beating of the heart, and may deliver a shock that could return the heart to a live-saving heart rhythm. Together, these two therapies may reduce the combined risk of death or first hospitalization as well as the risk of death alone. These devices also may relieve some of the symptoms associated with heart failure, thus resulting in an improved quality of life.



St. Jude Medical® Epic™ HF and Atlas® + HF Dual Chamber Implantable Cardioverter Defibrillator Systems with Cardiac Resynchronization Therapy - Approved June 2004, the Epic HF and Atlas + HF ICD Systems, manufactured by St. Jude Medical, Inc., are ICDs that also deliver CRT in patients with advanced heart failure. The systems consist of two parts: a pulse generator containing a battery and electronic circuitry, and three insulated lead wires that connect to the pulse generator. The pulse generator is usually implanted below the collarbone, just beneath the skin. One lead is placed in an upper heart chamber (the right atrium) and the two other leads are placed in each of the lower heart chambers (the ventricles). When the device functions as an ICD, it senses dangerous abnormal heart rhythms and shocks the heart back



Part 1. Technology and Innovation

into a normal rhythm. The CRT portion of the device coordinates the beating of the left and right ventricles so that they work together more effectively to pump blood throughout the body. The Epic™ HF and Atlas® + HF Systems should only be used with patients at risk for life-threatening cardiac rhythm problems who also have symptoms of advanced heart failure despite taking heart failure medication.



Stelid II, Stelix, and Stelix II Steroid Eluting Endocardial Pacing Leads -

Approved June 2004, the Stelid II, Stelix and Stelix II endocardial pacing leads, manufactured by ELA Medical, S.A., are surgically implanted wires that connect the heart to an implanted pacemaker. The lead allows a pulse



generator (pacemaker) to monitor the heart as it slowly releases a steroid (Dexamethasone Sodium Phosphate) into the body. The type of lead chosen is dependent on the pacing needs of the patient. A lead is inserted through a large vein connected to the heart. The leads have different methods of attachment depending on where the leads are being placed in the heart. The Stelid II leads (upper left) have a sharp prong tip (tine) that is inserted into the wall of a lower chamber of the heart (ventricle). The Stelix and Stelix II leads (upper right) are placed against the wall of the upper chamber of the heart (atrium). Once leads are placed in the heart and connected to an implanted pacemaker, the leads detect and transmit electrical signals from the heart to the attached pacemaker, and the pacing output from the pacemaker is sent through the leads to the heart. The steroid, Dexamethasone Sodium Phosphate (< 1.0 mg), located on the tip of the lead, is slowly released into the body. The Stelid and Stelix leads, along with the pacemaker, provide pacing threshold, pacing impedance, and sensing threshold values that are equivalent to controls with adverse event rates similar to control leads. The Stelix and Stelix II leads have equivalent or better electrical performance than controls and similar or fewer adverse events than controls.



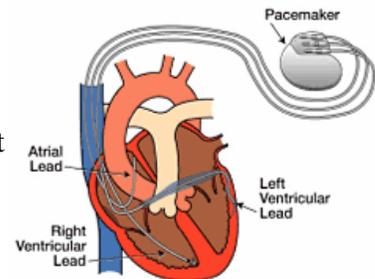
St. Jude Medical Frontier™ Biventricular Cardiac Pacing System -

Approved May 2004, the St Jude Frontier™

Biventricular Cardiac Pacing System, by St. Jude Medical, includes the

Frontier™ Model 5508 and 5508L Pulse Generators and

the Aescula™ LV Model 1055K Lead. The system is used to maintain simultaneous contraction of the lower chambers of the heart (left and right ventricles) following an atrial-ventricular (AV) nodal ablation for irregular heart rhythm such as chronic atrial fibrillation. The device consists of two parts: a pulse generator (pacemaker) containing a battery and electronic circuitry, and three insulated lead wires that connect to the pulse generator. The Frontier™ System should only be used to maintain simultaneous contraction of the lower



Part 1. Technology and Innovation

heart chambers in patients who have undergone an AV nodal ablation for chronic atrial fibrillation, and who have mild to moderate heart failure.

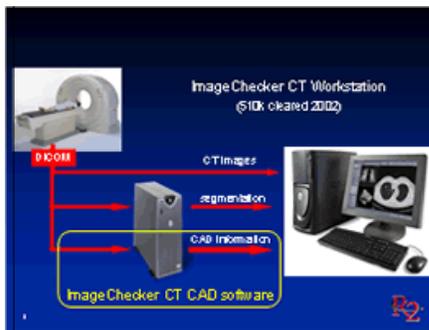


CONTAK® RENEWAL™ TR Models H120 and H125 -

Approved January 2004, the CONTAK® RENEWAL™ TR Models H120 and H125, by Guidant Corporation, are implantable pulse generators (IPG) that deliver cardiac resynchronization therapy (CRT). The CRT portion of the device uses small electrical pulses to coordinate the heartbeat and improve blood pumping ability in patients with moderate to severe heart failure. The

CONTAK® RENEWAL™ TR system is used in patients who have an electrical disturbance resulting in an irregular heart rhythm (arrhythmia) with moderate to severe heart failure that is not successfully treated with medication. The CONTAK® RENEWAL™ TR system may improve the quality of life for a patient by relieving some of the symptoms associated with heart failure.

Computed Tomography



ImageChecker® CT CAD Software System - In July 2004, FDA approved the ImageChecker CT CAD software system, manufactured by R2 Technology, Inc. The device is a new image analysis system designed to help radiologists review computed tomography (CT) images of the chest. The software system, the first-of-its-kind for use with CT chest exams, aids in the detection of solid nodules in the lungs. This is important because some lung nodules can be malignant. The system uses

computer aided detection (CAD) software to analyze CT images that the radiologist has previously reviewed, highlighting areas of the image that appear to be solid nodules. Because the device works independently of the radiologist, it can detect suspect areas that the radiologist may have overlooked.

Endoscopic and Surgical Instruments



Da Vinci Endoscopic Instrument Control System - In

July 2004, FDA cleared for marketing a robotic-like system to assist in coronary artery by-pass surgery. This device allows direct access to the chest using a standard open chest technique (sternotomy) or through a smaller surgical incision (thoracotomy). The Da Vinci Endoscopic Instrument Control System, manufactured by Intuitive Surgical Inc., enables a surgeon to perform heart surgery remotely while seated at a console with a computer and video monitor.

Part 1. Technology and Innovation

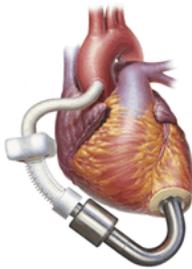
CoSeal™ Surgical Sealant - Approved December 2003, the CoSeal™ Surgical Sealant, manufactured by Baxter Healthcare Corporation, is a surgical sealant used to help stop leaks in blood vessels. It is made from two kinds of Polyethylene Glycol (PEG), the two PEGs are mixed together as they are applied during surgery to form a glue-like product, which seals leaks around sutures (surgical stitches), staples or other mechanical closure devices used in natural or artificial blood vessels (grafts).



Heart, Ventricular Assist



Syncardia Temporary CardioWest™ Total Artificial Heart (TAH-t) - The Syncardia Temporary CardioWest Total Artificial Heart (TAH-t), by SynCardia Systems, Inc., was approved in October 2004. The device is indicated for use in hospitalized heart transplant-eligible candidates at risk of imminent death from biventricular heart failure. The device may also improve kidney and liver functions because it restores blood flow to these vital organs—hence, making the patient a better candidate for eventual heart transplantation.



DeBakey VAD® Child – In February 2004, FDA approved the DeBakey VAD® Child by MicroMed Technology, Inc. under the Humanitarian Device Exemption (HDE) program. The DeBakey VAD® Child is intended for both home and hospital use in children who are between 5 and 16 years old, and who have end-stage left ventricular failure requiring temporary



mechanical blood circulation until a heart transplant can be performed. The device may allow children with severe left ventricular failure to survive long enough to receive a donor heart.

Contegra® Pulmonary Valved Conduit, Models 200 (unsupported) and 200S

(supported) - The Contegra® Pulmonary Valved Conduit, Models 200 (unsupported) and 200S (supported), manufactured by Medtronic Heart Valves, were approved in November 2003 as HDE devices. The pulmonary valved conduit device is a bioprosthesis (prosthesis made from biological material) heart valve made from a segment of bovine jugular vein that is treated with preservatives to keep it durable, flexible, and sterilized for human implantation. The Contegra Pulmonary Valved Conduit functions like a natural pulmonary valve. Three leaflets flap open to permit blood flow from the right ventricle into the pulmonary artery and then to the lungs. In conjunction with the three other heart valves (tricuspid, aortic, and mitral), this device controls the direction of blood flow through the chambers of the heart. The device



Part 1. Technology and Innovation

can be used in children and young adults under the age of 18 to correct or reconstruct the outflow of the right ventricle due to congenital heart malformations. It also can be used as a replacement for previously implanted but dysfunctional pulmonary homografts (valves from human cadavers) or valved conduits. Surgical replacement of the affected valve may improve a patient's medical condition and quality of life.

In Vitro Diagnostics

Ventana® Medical Systems' PATHWAY Anti-c-KIT (9.7) Primary Antibody -

Approved August 2004, the PATHWAY Anti-c-KIT (9.7) Primary Antibody, manufactured by Ventana® Medical Systems, Inc., contains an antibody used in a laboratory test that can help identify patients with [gastrointestinal stromal tumors \(GISTs\)](#) and select patients eligible for treatment with the FDA approved cancer drug [Gleevec®/ Glivec® \(imatinib mesylate\)](#). The antibody is used with an automated tissue staining system or manual assays and specialized staining accessories by a doctor trained to identify diseases, a pathologist, who analyzes tissue samples from patients suspected of having GISTs. The antibody detects a protein in the body that stimulates cancerous tissue cell growth (c-KIT tyrosine kinase). The presence of this protein, in association with other clinical information, indicates a diagnosis of cancer and eligibility for GISTs cancer treatment with Gleevec®/Glivec®.

NeoGram Amino Acids and Acylcarnitine Tandem Mass Spectrometry Kit – In August 2004, FDA cleared for marketing the NeoGram Kit. The kit is a laboratory blood test that will help doctors screen newborn infants for a variety of inherited diseases. The kit helps detect inborn errors in metabolism by measuring levels of amino acid, free carnitine and acylcarnitine. Abnormally high amounts of these substances, or abnormal patterns, may indicate different disease states including, but not limited to, phenylketonuria (PKU), maple syrup urine disease (MSUD), medium chain Acyl-CoA dehydrogenase deficiency (MCAD), isovaleric acidemia, homocystinuria and hereditary tyrosinemia. These diseases can result in developmental delay, seizures, mental retardation and death. Early identification may significantly improve long term outcome and quality of life.

CEDIA® Sirolimus Assay - Approved July 2004, the CEDIA® Sirolimus Assay, manufactured by Microgenics Corporation, is a laboratory test that can be used to measure concentration of the drug [sirolimus](#) in blood. Approved through the new de novo application process, this is the first new diagnostic test for an immunosuppressive drug developed in almost a decade. This test is used as an aid in the treatment of kidney transplant patients taking sirolimus and is the first FDA cleared sirolimus assay using immunoassay technology available in most central laboratories. Until now, sirolimus tests were performed only by specialized reference laboratories. Rapid monitoring of patients ensures proper treatment and helps in maintaining the integrity of transplanted organs. The assay is used together with other laboratory tests and patient evaluations to help determine if a patient is receiving an appropriate amount of sirolimus. The assay should not be used alone to make treatment decisions. It should be used in conjunction with clinical evaluation and other laboratory tests. Review of this product was followed by publication of a special controls guidance document to assist other sponsors in bringing like products to market. The assay can be used in kidney

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transplant patients who are taking sirolimus, at any time when estimating the blood level of sirolimus might help manage treatment.

bioMerieux VIDAS Total PSA Assay - Approved July 2004, the Vidas TPSA assay, by bioMerieux Inc., is an in vitro diagnostic test that measures Total Prostate-Specific Antigen (TPSA) in a blood sample. Prostate Specific Antigen (PSA) is an enzyme produced the prostate gland. Healthy men have low concentrations of PSA in their blood. This test is useful in the detection of prostate cancer in men aged 50 years and older, when used with digital rectal exam (DRE), an exam of the size and texture of the prostate.



OraQuick® Advance Rapid HIV-1/2 Antibody Test – In June 2004, FDA granted a Clinical Laboratory Improvement Amendments (CLIA) waiver to the oral HIV test by Orasure Technologies (approved by CBER). The waiver

extended the availability of the OraQuick Rapid HIV-1/2 Antibody Test from 38,000 laboratories permitted to perform the test to more than 100,000 sites, including physician offices, HIV counseling centers and community health centers. It is estimated that thousands of patients with undetected HIV infections will have increased access to testing and that earlier and broader identification will now be possible. This should allow for earlier treatment and better efforts to prevent spread of this disease.



QuickELISA Anthrax-Pa Kit - The Anthrax QuickELISA test kit, cleared for marketing in June 2004, detects antibodies produced during infection with *Bacillus Anthracis*, the bacteria that causes anthrax. The test, manufactured by Immunetics Inc., provides an easy-to-use clinical laboratory tool for assessing whether patients have been infected with anthrax, a serious potential bio threat pathogen.

GlucateLL™ - Approved May 2004, GlucateLL™, manufactured by Associates of Cape Cod Inc., is a blood test used in a medical laboratory or hospital, to help diagnose severe fungal infections. The GlucateLL™ test kit tests for Beta-glucan in the blood. Beta-glucan is found in the blood of patients who may have fungal infections or in patients that are at an increased risk for fungal infections (such as cancer, AIDS, or organ transplants). The serum, or liquid part of the blood is placed in a test chamber and chemicals are added that change color of the serum if Beta-glucan is present. If the test results are positive, doctors can perform other tests to determine what type of fungus is causing the infection. This test will not diagnose infections from types of fungus that do not produce Beta-glucan.

AxSYM Free PSA - Manufactured by Abbott Laboratories, the AxSYM Free PSA was approved in February 2004. The AxSYM Free Prostate Specific Antigen (free PSA) test is typically performed along with a total Prostate Specific Antigen (total PSA) test and a [Digital Rectal Exam \(DRE\)](#) to help distinguish between cancerous and non-cancerous (benign) prostate conditions. The free PSA test measures the amount of PSA that is not attached to

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other substances (free-floating) in the blood. The total PSA test measures the amount of PSA that is attached to proteins in the blood as well as the PSA that is in the free-floating form. Once both tests are completed, a doctor compares the free PSA result to the total PSA result to determine the percent free PSA (% free PSA). The % free PSA, combined with the total PSA value and a DRE, helps determine whether a [prostate biopsy](#) is needed to rule out the risk (in percent) of cancer. The smaller the % free PSA, the more likely the patient is to have prostate cancer. When used with a total PSA test and DRE, the AxSYM Free PSA test can help determine the risk of prostate cancer. The use of % free PSA is expected to reduce the number of unnecessary biopsies, while identifying those men who have an increased probability of having prostate cancer.

DakoCytomation EGFR pharmDx™ - Approved February 2004, the DakoCytomation EGFR pharmDx™, by DakoCytomation California, Inc., is used to identify colorectal cancer patients eligible for treatment with the cancer drug, ERBITUX™ (cetuximab). The EGFR pharmDx™ is a kit used by pathologists to analyze colon tissue samples. The kit detects protein in the body that stimulates cancerous tissue cell growth (Epidermal Growth Factor Receptor or EGFR). The presence of this protein indicates a patient is eligible for colon cancer treatment with ERBITUX™.

Heartsbreath - Approved as a HDE device in February 2004, Heartsbreath, manufactured by Menssana Research, Inc., is a breath test that is used along with a traditional heart (endomyocardial) biopsy on heart transplant recipients who have been transplanted less than one year. This test measures possible organ rejection in heart transplant recipients by measuring the amount of methylated alkanes (natural chemicals found in the breath and air) in a patient's breath. The Heartsbreath test may be used along with heart biopsy results to help guide short term and long term medical care of heart transplant recipients. The test's greatest potential value may be in identifying less severe organ rejection (grades 0, 1, and 2) from more severe rejection (grade 3).

Factor II (Prothrombin) G20210A Kit and Factor V Leiden Kit – In December 2004, FDA approved, through the new de novo application process, the first DNA-based laboratory tests for detection of genetic abnormalities in Factor V Leiden and Factor II (prothrombin) genes. The tests, manufactured by Roche Diagnostics Corp, are used in persons who have a history of abnormal blood clots or whose relatives have such a history. Factor V Leiden, is the most commonly tested genetic disorder in the US. Factor II, although less common, is also an important cause for blood clots. Availability of these tests allows routine laboratories to use standardized methods for rapid diagnose and better treatment for patients with these very important genetic disorders. Review of this product was followed by publication of a special control guidance document to assist companies in bringing future like products to market.

In Vitro Diagnostics- Hepatitis

ADVIA Centaur® Anti-HBs ReadyPack Reagents and Calibrators - Approved in September 2004, the Anti-HBs ReadyPack Reagents and Calibrators, by Bayer HealthCare LLC, are part of a laboratory test that detects antibodies to the Hepatitis B virus surface

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antigen (anti-HBs). Antibodies are produced by the body to fight against foreign substances called antigens, such as the [Hepatitis B virus \(HBV\)](#). The purpose of this test is to determine if the patient has been previously infected with HBV or is immune to HBV infection. This test is performed after vaccination against HBV or following an active infection. This test is intended to be only used on the Bayer ADVIA Centaur® System.

ADVIA Centaur® HBc IgM ReadyPack Reagents and ADVIA Centaur® HBc IgM ReadyPack Quality Control Materials - The ADVIA Centaur® HBc IgM ReadyPack Reagents and ADVIA Centaur® HBc IgM ReadyPack Quality Control Materials, by Bayer HealthCare LLC, were approved in August 2004. The reagent pack is a laboratory test that detects early antibodies associated with Hepatitis B virus (HBV) infection. IgM antibody to Hepatitis B core antigen (anti-HBc IgM) is an early antibody that normally appears during an HBV infection. Along with other tests for HBV infection, this test is used to follow the course of an HBV infection. The test is intended to be only used on the ADVIA Centaur® Immunodiagnostic system. The calibrator is a reagent that is used to set the analyzer so that it may distinguish between positive and negative results. This test helps to determine the stage of infection and what treatment may be needed. Depending on the results of this test and other testing the doctor may recommend anti-viral treatment.

VITROS Immunodiagnostic Products Anti-HBc IgM Reagent Pack and VITROS Immunodiagnostic Products Anti-HBc IgM Calibrator - The VITROS Immunodiagnostic Products Anti-HBc IgM Reagent Pack and VITROS Immunodiagnostic Products Anti-HBc IgM Calibrator, by Ortho-Clinical Diagnostics, Inc. were approved in March 2004. The reagent pack is a laboratory test that detects early antibodies associated with Hepatitis B virus (HBV) infection. IgM antibody to Hepatitis B core antigen (anti-HBc IgM) is an early antibody that normally appears during an HBV infection. Along with other tests for HBV infection, this test is used to follow the course of an HBV infection. This test is intended to be only used on the VITROS ECi Immunodiagnostic System. This test helps to determine the stage of HBV infection and what treatment may be needed. Depending of the results of this test and other testing, a doctor may recommend anti-viral treatment.

VITROS Immunodiagnostic Products Anti-HBc Reagent Pack and VITROS Immunodiagnostic Products Anti-HBc Calibrator - The VITROS Immunodiagnostic Products Anti-HBc Reagent Pack and VITROS Immunodiagnostic Products Anti-HBc Calibrator, by Ortho-Clinical Diagnostics, Inc. and approved in March 2004, is a laboratory test that detects early and late antibodies associated with Hepatitis B virus (HBV) infection. Antibodies are produced by the body to fight against foreign substances called antigens, such as HBV. This test is used along with other HBV tests to monitor the course of an HBV infection. This test is intended to be only used on the VITROS ECi Immunodiagnostic System. The calibrator is a reagent that is used to set the analyzer so that it may distinguish between positive and negative results. Depending of the results of this test and other testing, a doctor may recommend anti-viral treatment.

Abbott AxSYM® Antibody to Hepatitis C Virus - The Abbott AxSYM® Antibody to Hepatitis C Virus, manufactured by Abbott Laboratories, Inc., was approved in February 2004. The AxSYM® Antibody to Hepatitis C Virus (Anti-HCV) is a laboratory test used to

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help diagnose patients that may be infected with the Hepatitis C virus (HCV). This test detects antibodies associated with HCV. Antibodies are produced by the body to fight against foreign substances called antigens, such as HCV. The AxSYM® Anti-HCV tests a sample of the liquid part of a patient's blood (serum) and is analyzed by the AxSYM® System. Results from the AxSYM® Anti-HCV will help a doctor diagnose patients with an HCV infection. Positive results from the AxSYM® Anti-HCV should be followed up with additional tests to confirm past or resolved hepatitis infections from active HCV infections. AxSYM® Anti-HCV is not intended for use in screening blood, plasma or tissue donors because it has not proven effective for this use.

Mammography



Siemens Mammomat Novation DM Full Field Digital

Mammography System - In August 2004 FDA approved the Siemens Mammomat Novation DM Full Field Digital Mammography System, by Siemens MedicalSolutions USA, Inc. This device produces pictures of the breast using X-rays instead of film. This process uses detectors that change the X-rays into electrical signals, which are then converted to an image. Digital mammography is used for both screening and diagnosis.

From the patient's perspective, the procedure is the same as with ordinary mammography. The Siemens Mammomat Novation DR Full Field Digital Mammography System (Novation DR) is used with an approved X-ray system, the Siemens Mammomat 3000 Nova mammography system.

Ophthalmic

JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear - Approved October 2004, the JSZ Orthokeratology (oprifocon A) Contact Lenses, by Szabocsik and Associates, are rigid, gas permeable contact lenses used for orthokeratology, a process that temporarily corrects nearsightedness (myopia). The patient wears these lenses overnight and removes them in the morning. During the day, nearsightedness is temporarily corrected or greatly reduced. This may allow the user to not require the use of glasses or contact lenses during the day.



Verisyse™ Phakic IOL - Approved September 2004, the Verisyse™ phakic intraocular lens (IOL), by Ophtec USA Inc., is a plastic lens that is permanently implanted in the eye and attached to the iris to correct moderate to severe [nearsightedness \(myopia\)](#). It is called a phakic IOL because the eye's natural lens is retained. The Verisyse™ may improve a patient's distance vision without glasses or contact lenses.

INTACS® Prescription Inserts for Keratoconus - In July 2004, FDA approved the INTACS® Inserts, manufactured by Addition Technology, Inc. These inserts are two curved, clear plastic segments that are implanted in the perimeter of the cornea to reduce

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nearsightedness (myopia) and irregular steepening of the cornea (irregular astigmatism) caused by keratoconus. INTACS® Inserts are implanted through a small surgical incision on the perimeter of the cornea. The inserts help restore clear vision in keratoconus patients by flattening and repositioning the cornea. Approved under the HDE program, INTACS® Inserts are intended for patients with keratoconus who are no longer able to achieve adequate vision using contact lenses or glasses and for whom corneal transplant is the only remaining option. INTACS® Inserts may restore functional vision and postpone the need for a corneal transplant.

Euclid Systems Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear - Approved June 2004, the Euclid Systems Orthokeratology (oprifocon A) Contact Lenses, by Euclid Systems Corporation, are rigid gas permeable contact lenses used for orthokeratology, a process that temporarily corrects nearsightedness (myopia). The patient wears these lenses overnight and removes them in the morning. During the day, nearsightedness is temporarily corrected or greatly reduced. The Euclid Systems Orthokeratology (oprifocon A) Contact Lenses apply slight pressure to the center of the cornea, causing it to temporarily flatten. The flattened cornea redirects light onto the back surface of the eye (the retina) at an angle that can compensate for nearsightedness. Since the cornea is elastic, it gradually regains its shape throughout the day causing nearsightedness to return. Usually, patients must wear the lenses every night to maintain corrected vision.



Oculaid™ Capsular Tension Ring, or Stableyes™ Capsular Tension Ring - A first-of-a-kind device, approved in April 2004, the Capsular Tension Ring (CTR), by Ophtec USA, Inc., helps surgeons place and center an artificial intraocular lens in cataract patients who have weakened or missing zonules, the fibers of the eye that hold the lens in place.

Morcher Endocapsular Tension Ring - The Morcher Endocapsular Tension Ring, Types 14, 14A and 14C, manufactured by Morcher GmbH, were approved in October 2003. An Endocapsular Tension Ring (CTR) assists the cataract surgeon in placing and centering an intraocular lens, artificial lenses implanted to restore clear vision when the clouded natural lens is removed during cataract surgery. The device provides additional support to the capsular bag that surrounds the eye's lens. The CTR is intended for use in patients who have weakened or missing zonules, thin tissue fibers that hold the lens in place, supporting the capsular bag of the eye.



WaveLight ALLEGRETTO WAVE™ Excimer Laser System - The WaveLight ALLEGRETTO WAVE™ Excimer Laser System, manufactured by WaveLight Laser Technologies AG, was approved in October 2003. The device is a refractive excimer, or heatless, laser system that uses invisible ultraviolet (UV) light pulses to remove precise amounts of corneal tissue from the eye to reduce or eliminate farsightedness and

astigmatism.

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Osteoarthritis

Orthovisc® High Molecular Weight Hyaluronan - Approved February 2004, the Orthovisc® High Molecular Weight Hyaluronan, manufactured Anika Therapeutics, Inc., is a solution of sodium hyaluronate, a viscous substance that is naturally present in the knee joint. A doctor injects ORTHOVISC® into knee joints to relieve pain from osteoarthritis (OA) of the knee. ORTHOVISC® is used to treat pain from OA of the knee in patients who have not responded to pain reduction drugs like acetaminophen and non-drug treatments such as exercise and physical therapy.

Prostheses



Vertical Expandable Prosthetic Titanium Rib (VEPTR) - Approved August 2004 as a HDE device, the Vertical Expandable Prosthetic Titanium Rib (VEPTR), manufactured by Synthes Spine Co., is a surgically implanted device used to treat Thoracic Insufficiency Syndrome (TIS) in pediatric patients.

TIS is a congenital condition where severe deformities of the chest, spine, and ribs prevent normal breathing and lung growth and development. The VEPTR device is a curved metal rod that is attached to ribs near the spine using hooks located at both ends of the device. The VEPTR device helps straighten the spine and separate ribs so that the lungs can expand and fill with sufficient air to breathe. The length of the device can be adjusted as the patient grows.



Oxford™ Meniscal Unicompartamental Knee System - Approved April 2004, the Oxford™ Meniscal Unicompartamental Knee System, by Biomet Orthopedics, Inc., is an artificial mobile bearing knee system that replaces one side of the knee joint. The system has three parts: a metal curve-shaped part (femoral component), which a doctor cements onto the end of the thigh bone, a flat metal “tray” that is cemented onto the top of the shin bone (tibia), and a plastic support

(bearing) that sits on the tray and joins with the curved femoral component. The plastic bearing slides in between the tibial tray and femoral component, which allows the artificial knee joint to move. The Oxford™ Meniscal Unicompartamental Knee System reduces pain by replacing the painful arthritic portion of the knee joint, and restores movement of the knee joint.

Keramos™ Ceramic/Ceramic Total Hip System - The Keramos™ Ceramic/Ceramic Total Hip System, manufactured by Encore Medical, LP, was approved in November 2003. The device is an alumina ceramic artificial hip replacement system, surgically implanted to completely replace a diseased hip joint. The system has four parts that work together to allow the hip joint to move: a metal hip stem that is placed into a hole drilled in the end of the thigh bone; a ceramic, ball-shaped part (femoral head) that fastens to the metal hip stem; a



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ceramic, socket-shaped part (acetabulum) that the ball-shaped part fits in; and a metal shell that fastens the ceramic socket-shaped part to the hip bone. The ceramic ball slides around in the ceramic socket, allowing the artificial hip joint to move. The Keramos™ Ceramic/Ceramic Total Hip System is intended for patients who need a total hip replacement because of painful inflammatory or non-inflammatory arthritis.

Skin Fillers



Sculptra – In August 2004, after an expedited review, FDA approved Sculptra, manufactured by Dermik Laboratories, for use in human immunodeficiency (HIV) patients. Sculptra is an injectable filler intended to correct facial fat loss in HIV infected patients. The filler is the first such treatment approved for a condition known as lipoatrophy, or facial wasting, a sinking of the cheeks, eyes and temples caused by the loss of fat tissue under the skin. Lipoatrophy is common among HIV patients. FDA expedited review of the product because of its importance to people with HIV/AIDS.

Hylaform - Approved April 2004, Hylaform gel, by Genzyme Corporation, is a sterile colorless skin (dermal) filler made of chemically modified hyaluronic acid derived from an avian source. Hyaluronic acid is a naturally occurring substance found in cell and tissue fluids that is chemically, physically, and biologically similar in the tissues of all species. Hylaform gel is made from purified, natural hyaluronic acid that is gradually absorbed by the body. Hylaform is injected by a doctor into facial tissue where moderate to severe facial wrinkles and folds occur. The gel temporarily adds volume to the skin and can give the appearance of a smoother face.

Restylane® Injectable Gel - The Restylane® Injectable Gel, by Q-Med Scandinavia, Inc., was approved in December 2003. Restylane® is a transparent hyaluronic acid gel that is injected into facial tissue to smooth wrinkles and folds, especially around the nose and mouth. The gel works by temporarily adding volume to facial tissue. Its effect lasts for about 6 months. Restylane® is intended for use in areas of facial tissue where moderate to severe facial wrinkles and folds occur.

Spinal

PRECISION™ Spinal Cord Stimulator (SCS) System -

Approved in April 2004, the PRECISION™ Spinal Cord Stimulator (SCS) System, by Advanced Bionics Corporation, is a neurostimulation device that transmits electrical signals to the spinal cord to decrease chronic pain in the body, arms and legs. The device consists of two parts: a stimulator device (signal generator) implanted under the skin that transmits electrical signals to the spinal cord through an insulated lead wire; and an external remote control that programs the treatment delivered by the signal generator. The Precision™ SCS System is used as an aid in the management of difficult to treat chronic pain of the body and limbs, pain associated with failed back surgery syndrome, low back pain, and



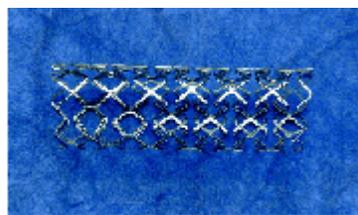
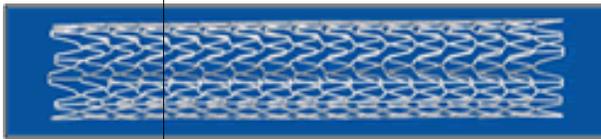
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leg pain. The Precision™ SCS System may decrease difficult to treat chronic pain in the body, arms, and legs.

OP-1 Putty - Approved April 2004 under the HDE program, the OP-1 Putty by Stryker Biotech, is used to make a new posterolateral spinal fusion in patients who have had a failed posterolateral spinal fusion. OP-1 Putty is made from a manufactured (genetically engineered) human protein powder, cow (bovine) collagen that is mixed with a sterile salt water (saline) solution, and a thickening agent to form a putty-like material. During surgery, the putty is placed on each side of the spinal levels that need to be fused. OP-1 Putty may help form a spinal fusion in patients who have failed a previous spinal fusion surgery, and are not able to provide their own bone or bone marrow for grafting because of a condition such as osteoporosis, diabetes, or smoking.

Stents

ACCULINK™ and RX ACCULINK™ Carotid Stent System - In August 2004, FDA approved the ACCULINK system, manufactured by Guidant Corporation. This device consists of two systems: a stent and delivery catheter system (ACCULINK™ and RX ACCULINK™ Carotid Stent System) and an embolic protection system (ACCUNET™ and RX ACCUNET™ EPS). The stent is a metal mesh tube placed on a delivery catheter. The embolic protection device is a micromesh filter basket on the end of a delivery catheter that catches any particles that may break off from the blockage during the procedure. FDA approved the stent for use in opening blocked arteries in the neck. The stent is intended to prevent stroke by treating blockages in the carotid artery, the main blood vessel leading to the brain. This first-of-a-kind device was approved for use in patients who have had symptoms of a stroke or whose carotid artery is at least 80 percent blocked, and who are not good candidates for the surgical alternative. The device is inserted during angioplasty, a less invasive procedure in which the stent is threaded up to the neck artery via a catheter inserted in the groin. Patients usually require only local anesthesia during placement of the stent.

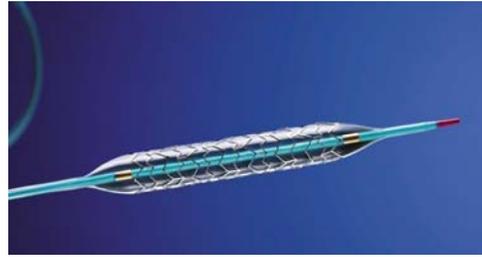


IntraStent® DoubleStrut™ Stent -The IntraStent® DoubleStrut™ Stent, manufactured by ev3 Inc., is a thin, flexible metal mesh tube that can be implanted in the large arteries that supply blood to the pelvis and legs (iliac arteries). Approved June 2004, the IntraStent® acts like a scaffold by holding an iliac artery open to maintain adequate blood flow. The IntraStent® is used to treat patients with iliac artery

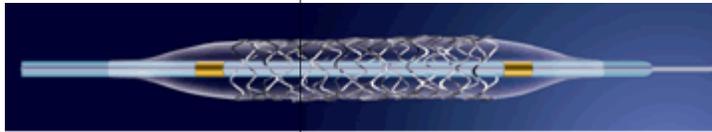
narrowing caused by atherosclerosis.

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TAXUS™ Express2™ Paclitaxel-Eluting Coronary Stent System (Monorail and Over-the-Wire) – In March 2004, FDA approved the TAXUS Express2™ Paclitaxel-Eluting Coronary Stent System (Monorail and Over-the-Wire), manufactured by Boston Scientific Corporation. The device is the second drug-eluting stent approved to open clogged coronary arteries.



NIRflex™ Premounted Coronary Stent System - The NIRflex™ Premounted Coronary Stent System, manufactured by Medinol Ltd., was approved in October 2003. The Coronary Stent System (CSS) consists of an expandable stainless steel tube (a stent), attached to a deflated balloon at the end of a long flexible tube (delivery catheter). The stent is used to open an abnormally narrowed artery by the accumulation of plaque in the artery wall and it becomes permanently implanted to hold open the artery.



Recent Device Approvals

The Recent Device Approvals website, www.FDA.Gov/CDRH/consumer/mda, contains information on recently approved devices, including:

- New Device Approvals, including some of the newest medical technology available
- Monthly listings of Premarket Notification [510(k)] and Premarket Approval (PMA) decisions
- Information on Humanitarian Device Exemption (HDE) approvals
- Searchable databases of devices previously approved for marketing or declared substantially equivalent to a legally marketed device.
- Frequently asked questions about recently approved devices.

Medical Device Review Programs

CDRH is responsible for the program areas through which medical devices are evaluated or cleared for clinical trials and marketing. Major program areas include Premarket Approval (PMA), Product Development Protocol (PDP), Humanitarian Device Exemption (HDE), Investigational Device Exemption (IDE), and Premarket Notification (510k). Information on these programs can be obtained through the Device Advice website, CDRH's self-service site

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for medical device and radiation emitting product information (<http://www.FDA.Gov/CDRH/devadvice/>.)

Major Submissions

In FY 04, CDRH received 8,436 major submissions. During the same period of time, we completed 8,573 major submissions. A breakdown on the number of major submissions received by program area is shown in Table 1. Table 2 lists numbers major submissions completed in each program area.

Table 1. Major Submissions Received (FY 99 – FY 04)

TYPE OF SUBMISSION	1999	2000	2001	2002	2003	2004
Original PMAs	64	67	71	49	54	51
PMA Supplements	557	546	641	645	666	635
Original IDEs	304	311	284	312	242	226
IDE Amendments	275	240	206	252	216	167
IDE Supplements	4,127	4,388	4,811	4,724	4,415	4312
510(k)s	4,458	4,202	4,248	4,320	4,247	3,635
Original HDE	12	11	5	5	10	9
HDE Supplements	4	10	16	16	29	29
Total	9,801	9,775	10,282	10,323	9,879	9,064

Table 2. Major Submissions Completed (FY 99 - FY 04)

TYPE OF SUBMISSION	1999	2000	2001	2002	2003	2004
Original PMAs	36	42	53	41	31	39
PMA Supplements	440	474	442	533	494	466
Original IDEs	305	320	284	307	246	221
IDE Amendments	268	251	207	251	217	162
IDE Supplements	4,224	4,335	4,803	4,711	4,424	4348
510(k)s	4,593	4,397	4,150	4,376	4,132	3,917
Original HDE	6	6	4	6	2	6
HDE Supplements	3	10	11	13	24	23
Total	9,876	9,835	9,954	10,238	9,570	9,182

Premarket workload and performance information is available at the Office of Device Evaluation website, <http://www.FDA.Gov/CDRH/ode/>, and at the Office of In Vitro Diagnostic Device (OIVD) Evaluation and Safety website, <http://www.FDA.Gov/CDRH/oivd/index.html>.

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Implementation of MDUFMA

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to provide FDA new responsibilities, resources, and challenges. MDUFMA was signed into law October 26, 2002. On April 1, 2004, the Medical Devices Technical Corrections Act (MDTCA), PL 108-214, was signed into law. MDTCA amends MDUFMA to clarify Congress's intent and to improve and expand upon some features of MDUFMA. In FY 04, CDRH invested time, attention, and resources on the implementation of MDUFMA.

MDUFMA has four particularly significant features:

- **User fees for premarket reviews** of PMAs, PDPs, premarket reports (a new category of premarket application for reprocessed single-use devices), Biologic License Applications (BLAs), certain supplements, and 510(k)s.
- **Performance goals** for many types of premarket reviews. These goals become more demanding over time, and include decision goals and cycle goals (cycle goals refer to actions prior to the final action on a submission).
- **Establishment inspections may be conducted by accredited persons** (third parties), under carefully prescribed conditions.
- **New regulatory requirements for reprocessed single-use devices**, including a new category of premarket submission, the premarket report.

MDUFMA Resources and Performance Goals

CDRH's medical device review programs benefited from the steady progress the Center has made in developing and deploying process improvements made possible by MDUFMA. Two of MDUFMA's key provisions are driving the improvements we are showing in our device review programs:

- **User fees for premarket reviews** of PMAs, PDPs, premarket reports, real-time PMA supplements, 180-day supplements, and 510(k)s have provided an important revenue stream that has allowed CDRH to increase our review capabilities and capacity by —
 - hiring more reviewers and more scientific, technical, and medical staff;
 - expanding training opportunities for our review staff; and
 - beginning to make long-needed improvements to critical data systems and support infrastructure.
- **Performance goals** for many types of premarket reviews have provided us a clear roadmap to where we need to take the program, and benchmarks that allow us to measure our progress over time. These goals were developed collaboratively with industry and Congress, and provide a common framework for measuring our performance. Our goals become more demanding over time, and include FDA decision goals and cycle goals.

MDUFMA has provided the device program much greater visibility, and the support it has garnered from industry, the Administration, and Congress is the primary reason why the

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President's Budget for FY 05 proposed, and Congress enacted, an *increase* of more than \$23.8 million (over FY 04) for the medical device program. With increased appropriations and user fees, CDRH will have the means to hire additional staff, expand training opportunities, improve review processes, provide more interactive reviews, provide new and updated guidance documents, rebuild and expand the support infrastructure, begin to lay the foundation for electronic reviews, and much more. MDUFMA makes these improvements possible.

For additional information, including the latest report on progress in meeting MDUFMA's performance goals, visit www.FDA.Gov/CDRH/mdufma.

During FY 04, CDRH took many actions as we worked to provide guidance, improve our review processes, and build and expand essential data systems and other infrastructure. These actions set the stage for the hard work we face to meet MDUFMA's FY 05 and later performance goals. Among our most notable actions, we:

- published 28 *Federal Register* notices to keep the public informed of our plans and actions in implementing MDUFMA;
- published 3 new draft guidance documents, 7 new final guidance documents, and 2 updated final guidance documents;
- held our first annual meeting with MDUFMA stakeholders (covering FY 03),
- submitted a report to Congress summarizing our performance against MDUFMA's goals during FY 03; and
- submitted a report to Congress summarizing the financial position of the MDUFMA program.

The efforts invested in these and similar activities during FY 03 and FY 04 are already producing measurable improvements in the timeliness, predictability, and quality of our device reviews. We are meeting or exceeding our MDUFMA performance goals, and we intend to continue to work towards achieving the more difficult goals for FY 05 through FY 07.

CDRH carefully monitors performance against all of MDUFMA's performance goals, even those that have not yet gone into effect. At the end of each quarter, we report on all workloads that are, or that eventually will be, subject to a performance goal. We provide information on receipts, actions we have taken, how those actions compare with the applicable performance goal, and other information. Progress to date has been encouraging, particularly the improvement shown for the FY 04 receipt cohort.

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MDUFMA Performance Goals

These tables show our progress towards meeting MDUFMA’s performance goals. They provide a comparison of performance for the FY 03 and FY 04 receipt cohort. All key indicators show modest, but consistent, improvement from FY 03 to FY 04. Additional information is available at the MDUFMA website, <http://www.FDA.Gov/CDRH/mdufma>.

Table 3. PMA Performance Goals

	Decision Goals FY 2006 Goal: 80% of FDA decisions within 320 FDA days (Decision = approval, approvable, approvable pending GMP, not approvable, denial) (as of 9/30/2004)	Cycle Goals (as of 9/30/2004)
FY 03 Cohort	<ul style="list-style-type: none"> • 47 Original PMAs and P-T Supplements filed • 41 FDA decisions; 6 pending applications <ul style="list-style-type: none"> • % of decisions meeting goal: 95% • % of cohort meeting goal (to date): 83% • % awaiting MDUFMA decision: 13% 	<ul style="list-style-type: none"> • 25 1st action = major deficiency letter <ul style="list-style-type: none"> • % of actions meeting goal: 84% • FY 2005 Goal: 75% within 150 FDA days • 22 “all other” 1st actions <ul style="list-style-type: none"> • % actions meeting goal: 96% • FY 2005 Goal: 75% 180 FDA days • FY 2003 first action cohort is <i>closed</i>
FY 04 Cohort	<ul style="list-style-type: none"> • 41 Original PMAs and P-T Supplements filed • 11 FDA decisions; 30 pending applications <ul style="list-style-type: none"> • % of decisions meeting goal: 100% • % of cohort meeting goal (to date): 27% % • awaiting MDUFMA decision: 73% 	<ul style="list-style-type: none"> • 20 1st action = major deficiency letter <ul style="list-style-type: none"> • % of actions meeting goal: 85% • FY 2005 Goal: 75% within 150 FDA days • 12 “all other” 1st actions <ul style="list-style-type: none"> • % actions meeting goal: 100% • FY 2005 Goal: 75% 180 FDA days • 9 with first action pending (22% of cohort)

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Table 4. 510(k) Performance Goals

Action	FY03 Performance	FY04 Performance	FY 05 Goal
Final decision <90 days	76%	89%	75%
First action <75 days	58%	78%	70%
Second action <60 days	50%	81%	70%
		29% of cohort awaiting final decision as of 9/30/04	

New Option for Obtaining Quality Systems Inspections

MDUFMA authorizes FDA-accredited persons to inspect qualified manufacturers of class II and class III devices. These provisions are intended to help FDA focus its limited inspection resources on higher-risk inspections and give medical device firms that operate in global markets an opportunity to more efficiently schedule multiple inspections.

A third-party inspection will cover the same quality systems requirements as an FDA inspection, and will be no less stringent than an FDA inspection. The accredited person who conducts the inspection will report to FDA, and FDA retains the sole responsibility for determining whether a manufacturer is in compliance with FDA's Quality Systems Regulation and other regulatory requirements, and whether voluntary or official action is required to correct observed deficiencies.

A third-party inspection will provide manufacturers greater control over the timing of their inspection, and because a third-party inspection may be completed in phases over a two-year period, the manufacturer should be able to better coordinate inspection activities with their firm's normal production practices and better accommodate the schedules of key personnel. If a firm uses a third-party that is both accredited by FDA and recognized by another country, it is possible that a single third-party inspection will meet the requirements of both FDA and another regulatory authority, thereby reducing or eliminating the need for multiple inspections of the same establishment. Manufacturers may also be able to coordinate a third-party inspection with other quality initiatives, such as audits to obtain or maintain ISO 9001:2000 certification.

Strict provisions to prevent conflicts of interest, establishment eligibility criteria, provisions for continued periodic FDA inspections, and careful FDA oversight all work together to ensure the integrity of the third-party inspection program.

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During FY 04, we completed the work necessary to launch the third-party inspection program and:

- accredited 15 third-parties who can now to conduct Quality Systems / GMP inspections under MDUFMA; we provide a current list of all accredited third-parties on our Internet site, www.FDA.Gov/CDRH/ap-inspection/ap-inspection.html#list;
- published draft guidance explaining how a firm may request a third-party inspection; the guidance is available on our Internet site, www.FDA.Gov/CDRH/comp/guidance/1532.pdf; and
- revised and updated our guidance that provides and explains the criteria we apply in accrediting a third-party to conduct inspections; our current guidance is available at www.FDA.Gov/CDRH/mdufma/guidance/1200.pdf.

As a result of these actions, manufacturers may choose to obtain a third-party inspection rather than an FDA inspection. We encourage qualified establishments to consider this flexible and innovative option. Additional information on FDA's third-party inspection program is available at www.FDA.Gov/CDRH/ap-inspection.

Strengthened Oversight of Reprocessed Single-Use Devices

One of the more important changes made by MDUFMA was to provide FDA with greater oversight authority to help ensure the safety and effectiveness of reprocessed single-use devices. Before enactment of MDUFMA, the regulatory requirements for manufacturers of reprocessed single-use devices (the persons who are reprocessing the device) was dependant upon the class of the device. Manufacturers of reprocessed class I and II single-use devices were required to have a 510(k), unless the device was exempt from 510(k). Reprocessors of class III devices were required to obtain premarket approval.

MDUFMA required us to undertake a comprehensive examination of exemptions from our 510(k) premarket notification requirements. As a result, we revoked many of the past exemptions and 510(k)s are required for some class I and class II reprocessed devices, including devices that were on the market prior to enactment of MDUFMA. Furthermore, the law required "validation data" in new 510(k)s to demonstrate that a reprocessed device will remain safe and effective for each additional intended use. If a reprocessed device was cleared through the 510(k) process prior to MDUFMA, the law also required validation data to be submitted to CDRH or the device could no longer be marketed. Reprocessors of class III devices are required to submit a premarket report (a new type of premarket application that includes requirements that focus on the special characteristics of reprocessed devices).

During FY 04 we:

- identified the semicritical devices whose exemption from 510(k) premarket notification should be terminated (we did the same for *critical* devices during FY 03), and we published a *Federal Register* notice listing the devices whose exemption was terminated and for which validation data are required in a 510(k); we provide the notice on our Internet site at www.FDA.Gov/OHRMS/DOCKETS/98fr/04-8307.pdf; and

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- revised and updated our guidance on how validation data should be provided in new 510(k)s for reprocessed single-use devices; our current guidance is available at www.FDA.Gov/CDRH/ode/guidance/1216.pdf.

Additional information on FDA's oversight of reprocessed single-use devices is available at www.FDA.Gov/CDRH/reuse.

Medical Devices Advisory Committee

The Center's Medical Devices Advisory Committee (MDAC) with its 18 panels provides clinical and scientific advice to FDA in a number of areas fundamental to the regulation of medical devices. The primary areas of activity are: (1) review and recommendations on premarket submissions, primarily Premarket Approval Applications (PMAs), and 510(k)s, (2) classification and reclassification of medical devices based on risk to patients, (3) advice on guidance documents that provide industry and FDA staff with expectations for studies and data for premarket reviews, and (4) input on new issues or questions concerning the determination of the safety or effectiveness of medical devices.

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

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

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

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Postmarket Surveillance Programs

Medical Product Surveillance Network (MedSun)

The FDA Modernization Act of 1997 (FDAMA) directed FDA to change the current MDR regulation pertaining to user facilities from a required universal reporting system to a system comprised of a subset of user facilities. Since February 2002, CDRH has been collecting data about medical devices problems from a sample of hospitals and nursing homes. This data collection initiative, called the Medical Product Surveillance Network (MedSun) is an interactive, internet-based reporting program. CDRH has collaborated with these facilities to determine the effectiveness of various incentives and types of feedback on the quantity and quality of reports sent into the system.

During FY 04, CDRH continued recruitment of reporting facilities from the east coast and mid-west region of the United States, for a total of 180 facilities. Additionally, in FY 04 a pilot project was begun to directly target the submission of reports from laboratories (pathology and in vitro diagnostic tests) in the reporting hospitals. By the end of the fiscal year, 299 sites had been recruited with representation nationwide. The laboratory pilot determined that it was very important for CDRH to receive the type of information that was collected during the pilot. Therefore, special emphasis on increasing the reporting from hospital laboratories will take place in FY 05. Numerous regulatory and non-regulatory initiatives have taken place based on reports received in the MedSun program.

Adverse Event Reports

During FY 04, FDA received approximately 57,600 individual medical device adverse event reports from manufacturers, user facilities, and importers. Additionally, 3,887 voluntary adverse event reports were submitted by health care professionals and consumers. CDRH postmarket staff reviewed and analyzed these reports to determine actual and potential public health risks associated with reported device problems. If the use of a particular product results in unexpected problems or risks, CDRH follow-up is undertaken to determine the etiology of a reported problem and to determine appropriate solution strategies.

This fiscal year, adverse event review and analysis identified significant problems with a number of issues:

- A patient lift that malfunctioned and fell on a patient resulting in an import alert and recall of the products.
- Contamination of a sealed blister pack of needles resulted in CDRH working with the firm to improve manufacturing processes to ensure a safe product.

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- Dislodgement of powered toothbrush heads associated with patient injuries resulted in manufacturer recall of the product.
- Accidental misconnections with intravenous and oxygen tubing resulted in CDRH working with the manufacturer to issue a safety letter to users.
- Paralysis associated with the use of absorbable hemostatic agents to stop bleeding during surgery resulted in CDRH issuance of a public health notification to healthcare practitioners.
- Fires involving electrically powered hospital beds resulted in CDRH issuance of a public health notification to healthcare practitioners with safety tips for prevention.
- The occurrence of thrombosis and hypersensitivity associated with a drug eluting stent resulted in a CDRH public health web notification to physicians.

CDRH also published articles in a device safety column in a peer-reviewed clinical journal alerting healthcare practitioners to identified problems with

- inappropriate use of patient controlled analgesia infusion pumps resulting in medication overdoses;
- inadvertent injection of air into intravenous tubing during contrast media injections;
- the occurrence of peritonitis associated with continuous cyclic peritoneal dialysis therapy by patients in the home;
- patient use of decorative contact lenses without a prescription or professional fitting resulting in eye injury, vision impairment and blindness;
- electrical hospital bed fires associated with overheating of bed motors and use of damaged connection plugs; and
- inadvertent misconnections of intravenous tubing with tubing of other devices resulting in misadministration of medications associated with adverse patient outcomes.

In addition, problems with aortic anastomosis devices used during cardiac surgery were presented at a CDRH cardiovascular panel meeting convened to obtain panel recommendations and guidance for evaluating prospective manufacturer post-market study designs.

Alternative Summary Reporting

CDRH continued to accept more reports into the Alternative Summary Reporting (ASR) program. In this program, manufacturers submit abbreviated reports in a line item, aggregated way. This program is for devices with problems that are well-known and well-documented. Examples of such problems include

- shearing of central line catheters;
- endosseous implants failing to osseointegrate; and
- breast implant ruptures.

Approximately 58 manufacturers participate in this program for about 50 different types of classified devices. Four manufacturers are currently participating in the electronic version of ASR and twelve firms are using a newly developed CD-ROM based submission process.

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CDRH received and entered approximately 99,000 line item reports in the summary database in FY 04.

Postmarket Issue Action Teams

The CDRH Issues Management Staff (IMS) is responsible for leading, coordinating, and facilitating the examination of postmarket problems to determine solution strategies for Center actions to protect the public health. The primary vehicle used by IMS to fulfill this responsibility is the interdisciplinary expert working group or Postmarket Issue (PMI) Action Team (formerly known as the Ad Hoc Committee). Postmarket Issue (PMI) Action Teams develop a Center perspective on a safety issue with a marketed medical device or radiation-emitting product and determine the most effective approach to mitigating risk to the public health. A PMI Action Team may be product-specific, or may pertain to a general category of devices. PMI Action Teams, staffed with appropriate clinical, scientific, technical, and regulatory expertise, are convened to:

- confirm that the issue has potential public health impact, requiring Center-wide participation to manage it;
- delineate the nature and extent of the issue, if possible; and
- develop recommendations for solution strategies for Center management decision-making.

In 2004, CDRH PMI Action Teams addressed many diverse issues with marketed medical devices. Some examples include:

- infection and injury associated with breast pumps;
- fires with hospital beds and anesthesia gas machines;
- endotoxin in devices used for LASIK;
- counterfeit polypropylene surgical mesh;
- the interaction of medication delivery patches and deep brain stimulators with MRI;
- potentially life threatening adverse events associated with an aortic connector for anastomosis in cardiac by-pass grafting; and
- problems with a cerebral aneurysm embolization device.

International Programs

In FY 04, CDRH developed a plan to help meet the goals of the CDRH portion of the agency's International Agenda. The plan, which includes a priority list and a schedule of international activities taking into account the public health impact of each activity, helped direct the CDRH International Staff to high priority activities.

Joint Inspection Program

The Joint Inspection Program exists under the United States (US) / European Community (EC) Mutual Recognition Agreement (MRA). During FY 04, CDRH:

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- trained and evaluated the European Union (EU) Conformance Assessment Body (CAB) auditors through the joint inspection program; and
- established a team to conduct on-site evaluations of US CABs.

International Vigilance Report

The National Competent Authority Report (NCAR) exchange program includes 16 nations, 13 of whom actively initiated reports during FY 04. In FY 04, CDRH issued over 20 and received over 100 NCARs. Providing approximately 16% of the NCARs exchanged in 2004, CDRH remains among the top contributors to the NCAR program. The NCAR subject devices varied in FY 04, though in vitro devices seemed to dominate the reports. Other devices in NCARs included:

- Breast implants
- Closure devices
- Dental implants
- Disinfection solutions
- Glucose monitors
- Hemodialysis
- Hospital beds
- Implantable cardio-defibrillators
- Implantable pumps
- Incubators
- Intraocular lenses
- Lasers
- Orthopedic implants
- Umbilical clamps

Global Harmonization Task Force

The Global Harmonization Task Force (GHTF) was formed in 1992. The founding members are the United States, Canada, the European Union, Japan, and Australia. Other nations participate as liaison members and observers.

GHTF encourages convergence of medical device regulatory practices worldwide where possible, while ensuring the safety, effectiveness, and quality of medical devices. Four distinct study groups (SG) develop guidance documents on basic regulatory practices.

Each study group focuses on a different aspect of medical device regulation:

- Study Group 1: regulatory and premarket requirements;
- Study Group 2: postmarket vigilance;
- Study Group 3: quality systems; and
- Study Group 4: regulatory auditing of quality systems.

The United States, through CDRH, remains a major partner in GHTF. Throughout FY 04, CDRH actively participated in the work of each of the four SGs, as well as the steering

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committee, which provides oversight to all GHTF activities. GHTF and SG information can be obtained at <http://www.ghf.org>.

CDRH plans to continue full participation in the advancement of the GHTF's mission and initiatives, such as was demonstrated by the NCAR program, which shares significant global postmarket device information.

Global Medical Device Nomenclature

CDRH continued working towards the eventual adoption of Global Medical Device Nomenclature (GMDN). Staff who represent CDRH in the GMDN Maintenance Agency were also involved in CDRH nomenclature activities. Improvement and expansion of the GMDN was expedited by new web-based computer application that allows the input of hundreds of new device names/definitions from proposals submitted world-wide, and the modification of existing device names/definitions in the ongoing process to accurately link CDRH procodes in the GMDN.

The Emergency Care Research Institute (ECRI) continued to assist CDRH in its work on product codes (procodes) in the GMDN, and in the general improvement of the nomenclature's structure. Efforts were also made to include the GMDN in the National Library of Medicine's Unified Medical Language System (UMLS).

The GMDN consists of nearly 19,000 terms, almost 8,000 of which are preferred terms with definitions used for product identification. Within CDRH, a computerized form of device definition elements was developed to accompany new procode requests for the promotion of more informative device definitions, in alignment with those of the GMDN.

Postmarket Collaborations

Drug-Eluting Stents

CDRH and the American College of Cardiology (ACC) continued to study drug-eluting stents within the ACC's National Cardiovascular Data Registry (ACC-NCDR). The ACC-NCDR is a confidential quality measurement program for cardiovascular specialists, hospitals, and cardiac catheterizations laboratories for collecting information on practice patterns and outcomes. The registry collects 142 core data elements needed for measuring the clinical management and outcomes of patients undergoing diagnostic cardiac catheterizations and percutaneous coronary interventions. The ACC-NCDR consists of over 1.4 million patient records. CDRH currently has a contract with ACC to access data with specific patient- and procedure-level information to examine the prevalence of use and the experience of patients with drug-eluting stents.

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Hospital Bed Safety

Death and injury adverse events associated with patient entrapment in hospital beds continue to be reported to CDRH. The Hospital Bed Safety Workgroup (HBSW), under CDRH's leadership and in partnership with hospital bed manufacturers, national health care organizations, patient advocacy groups, the Department of Veterans Affairs and Health Canada, undertook a series of studies to validate the test methods and various measurement tools to be used to evaluate openings in hospital beds. HBSW will make available the final test methods and tool to the public in FY 05.

During FY 04, CDRH accepted public comment on the draft guidance for industry entitled "Hospital Bed System Dimensional Guidance to Reduce Entrapment." This guidance, based on HBSW's expertise, provides recommendations for the manufacturers of hospital beds and hospital bed accessories to reduce life-threatening entrapments associated with hospital bed systems. It identifies the parts of the body at risk for entrapment, the locations of gaps or openings, and recommends dimensional criteria for beds.

CDRH's website for bed safety provides information and links to clinical information and educational materials to identify and reduce the risk of patient entrapment in hospital beds at www.FDA.Gov/CDRH/beds/.

Postmarket Epidemiology

CDRH epidemiologists conduct applied epidemiologic research using a variety of methods and databases and provide consultative services to the Office of Device Evaluation (ODE) and other CDRH Offices on issues requiring epidemiological expertise, from systematic reviews of the literature to risk assessments to the design and conduct of observational studies. Major epidemiologic research during the past year that resulted in publications in scientific journals and presentations at national professional meetings include: serious injuries associated with the use of hemostasis devices; the epidemiology of tampon associated toxic shock syndrome; an active surveillance system to detect medical device associated adverse events that are generally undetectable through routine surveillance; breast implant rupture; evaluation of the completeness of studies undertaken by industry as a condition of premarket approval of their products; use of the National Electronic Injury Surveillance System (NEISS) to assess the frequency of injuries due to medical devices; uses and outcomes associated with transmyocardial revascularization; adverse events related to central venous catheters; adverse events related to breast pumps; adverse events related to infusion pumps; adverse events associated with the Smallpox vaccine; adverse events associated with surgical staplers; the public health impact of a continuous glucose monitoring system; and aneurysm-related mortality associated with an endovascular graft.

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Conditions of Approval Pilot Project

As part of CDRH's effort to formalize Total Product Life Cycle (TPLC) precepts within the premarket review process, ODE's Division of Reproductive, Abdominal, and Radiological Devices (DRARD) continued to refine the cooperative project with the Epidemiology Branch (EB) of the Office of Surveillance and Biometrics. The purpose of this collaboration was to continue EB involvement in the review process of potential postmarket investigations including initiation and evaluation of the product-specific postmarket plans. Over the course of this year, each epidemiologist participated in the review of a PMA being evaluated by DRARD. Four PMAs that were approved during the year had post-approval studies. In all cases, the epidemiology reviewer developed a detailed plan for the postmarket follow-up of the specific device and played a large role in the post-approval study design. For the PMAs that were part of the original DRARD pilot and were approved last year, the epidemiologists continued to follow and monitor the progress of the initiated post-approval studies. There were six follow-up reports completed (one 6-month report, three 12-month reports, and two 18-months reports) on the status of the postmarket experience with the specific devices. Epidemiologists closely collaborated with Product Evaluation Branches analysts to incorporate their analysis of the adverse event reports into the final postmarket follow-up report.

Medical Errors

CDRH met with and educated medical device manufacturers on the importance of implementing human factors engineering (HFE) principles in order to reduce use errors. We worked with manufacturers and informed them about the HFE program and the regulatory status of human factors.

Our primary efforts in FY 04 were as follows:

- Worked with the Association for Advancement of Medical Instrumentation (AAMI) HFE Standards Committee and AAMI Staff Education Professionals. We participated in 5 teleconferences to plan for the AAMI Human Factors Engineering Conference to be held in Washington, DC in June 2005 and a mirror conference to be held in Germany in March 2005.
- Presented an overview of the FDA's HFE program at the *Human Factors Personal Medical Device Workshop* sponsored by the University of Maryland Department of Computer Sciences.
- Participated in the Medical Simulators Conference in May 2004 by presenting on the human factors issues of good stimulator design. The conference was sponsored by the Center for Telemedicine Law and the Army Medical Materials Command in Ft. Dietrick, MD.
- Presented a discussion on usability validation issues at the Symposium on the Plug and Play O.R. of the Future – an academia, industry and government organization that discusses what must be done in order to advance the concept of plug and play medical

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- devices and make it possible to integrate devices into one system that maintains a consistent user interface.
- Assisted in educating the visiting UK Medical Regulators - Presented an overview of the FDA's HFE program.
 - Presented at the AAMI Conference and Exposition in which patient safety was the theme. The symposium, "Engineering Safety into the Healthcare Process", included 5 other speakers and was presented by the allied group American College of Clinical Engineers (ACCE).
 - Presented Understanding "No Problem Found" Human Factors in Medical Device Use Error to MEDSUN constituency via audio teleconference.
 - Presented HFE display at FDA/AAMI International Standards and Regulations Conference in March 2004.

Electronic Labeling

During FY 04, CDRH researched optimum ways of presenting electronic labeling on websites. On November 18, 2003, we hosted the "Medical Device Electronic Labeling Conference." The purpose of the conference was to learn about current best practices for conveying medical device information electronically to health care professionals, patients, and consumers. Five experts from the public and private sectors presented information about research-based web design and usability guidelines, user-centered design issues, and writing style and format for web-based applications. The content of the conference is captured in a summary report. Attendees included representatives from all FDA Centers. Next steps include:

- preparation of electronic labeling prototypes;
- heuristic assessment of the prototypes of electronic labeling; and
- usability testing comparing prototypes of electronic labeling to model versions of paper-based labeling presented on the web.

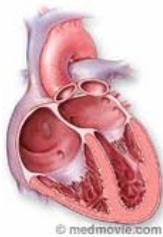
Part 3. Communicating Medical Technology (CDRH Strategic Goal: Knowledge Management)

Access to Information

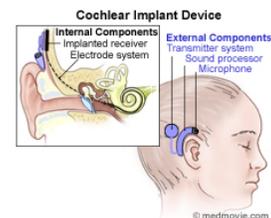
CDRH Disease-Specific and Hot Topic Websites

CDRH's Center-wide e-Consumer initiative is designed to improve access to electronic information. As new technology emerges, it is not only our responsibility to assure its safety and effectiveness, but also to communicate its existence and usefulness to the public at large. In FY 04 we:

- Launched the Office of In Vitro Diagnostic Device (OIVD) Evaluation and Safety website (<http://www.FDA.Gov/CDRH/oivd/index.html>), which contains information on regulatory activities, new items, and laboratory safety tips. The website also offers access to databases that provide information on products cleared for over-the-counter use, CDRH review summaries for cleared IVDs, and recent compliance actions.
- Continued to develop and maintain the website on diabetes (www.FDA.Gov/diabetes), combining information from all FDA Centers into one location for easy access and usability. The website records approximately 4,000 to 6,000 visits per month, and many government and consumer websites link directly to it. This site is now being used as a model for future disease-specific websites at FDA.
- Launched the cardiovascular disease website (www.FDA.Gov/hearthealth) which combines information from all FDA centers into one location for easy access and usability. This website is enhanced by extensive graphics showing the function of the healthy heart, the diseased heart, and medical interventions. It was posted in February 2004 and receives approximately 3,000 visits per month.



- Launched a new website on cochlear implants (www.FDA.Gov/CDRH/cochleaer) which provides information for consumers, educators, and health professionals about the risks and benefits of cochlear implants. The site was posted in September 2004.
- Published the newsletter FDA & You for the second year. This newsletter targets secondary school students and health educators. Issued three times a year, FDA & You provides information on FDA topics of interest to teenagers and is available at www.FDA.Gov/CDRH/fdaandyou/index.html. In April 2004, a mailing of 62,000 postcards invited health educators and secondary school



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principals to read the newsletter and view it online.

In November 2004, FDA & You was featured at the

American Public Health Association convention in Washington, DC.

- Updated the Breast Implant Handbook and the Breast Implant Brochure for consumers. Both the handbook and the brochure alert prospective breast implant recipients of the known consequences and presents pictures of three frequent adverse outcomes. Both documents are available on the internet at <http://www.FDA.Gov/CDRH/breastimplants/indexbip.html>.
- Continued updating the Medical Device Safety website (www.FDA.Gov/CDRH/patientsafety/), which enables health care professionals to find CDRH's medical device safety information, e.g., recalls, public health notifications, safety tips, "Dear Doctor" letter, in one consolidated website. The site is updated regularly to feature high priority risk messages. During this year, CDRH analyzed the target audience and evaluated site usability, with the aim of redesigning the site to make the information more accessible and understandable to practitioners.



FDA Breast Implant
Consumer Handbook

2004

FDA Premarket Decision Summary Templates

In an effort to empower consumers making decisions regarding the use of In Vitro Diagnostic Devices, such as “predicates” and diagnostic kits to be used professionally or at home, and to be consistent with CDRH’s center-wide “Knowledge Management” and “Transparency” initiatives, OIVD developed and implemented the use of a standardized Premarket Decision Summary Template across all the OIVD divisions.

The Premarket Decision Summary Template summarizes the basis on which an In Vitro Diagnostic Device was cleared under a 510(k) submission. OIVD implemented the use of this standardized premarket Decision Summary Template in August 1, 2003. The decision summaries have been continuously posted on the OIVD webpage and the public has full access to them. CDRH has been receiving positive feed back from the regulated industry, the professional community and the consumers because the decision summaries had given them the ability to make informed decisions regarding the use of such In Vitro Diagnostic Devices as “predicates” and diagnostic kits to be used professionally or at home.

FDA Patient Safety News (FDA PSN)

CDRH leads the agency production of FDA Patient Safety News (www.FDA.Gov/psn), a monthly television news show distributed to health care practitioners. FDA PSN is a major agency vehicle for communicating safety messages on medical products to physicians, nurses,



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pharmacists, risk managers and educators across the nation. Now in the third year of production, PSN incorporates stories from CDER, CDRH and CBER on medical errors, patient safety, recalls and alerts, and newly approved drugs, devices and biological products. Since its inception in 2002, FDA PSN has covered over 250 separate stories designed to reduce medical errors and improve the safety of FDA-regulated medical products. This year, FDA PSN received an Award of Excellence from National Association of Government Communicators. The show is broadcast each month on several medical satellite TV networks that bring continuing education for health professionals to over 4,500 U.S. hospitals and long-term care facilities. The show also has its own website (www.FDA.Gov/psn), which received about 6,000 visits per month in FY 04, an increase of about 50% since FY 03. On the site, users can view current or past editions of the show, search for individual stories, get more information on any story, email stories to other people, and report problems through MedWatch. This year, users were able to download a video story for later viewing.

Over 2,500 website users have joined a listserv to be automatically notified about the release of each month's show. A FY 04 survey of listserv subscribers indicated that 94 % of respondents used the FDA PSN safety recommendations "frequently" (41 %) or "occasionally" (53 %).

Public Health Notifications

The Public Health Notification (PHN) is one of the tools that CDRH uses to get an important message to the user community about risks associated with use of medical devices. PHN is a source of information for health care practitioners, immediately recognizable as a statement from the FDA about a device risk with information on how to avoid or mitigate the risk. This outreach tool is used when:

- The Center has information or a message to convey to health care practitioners that they would want to know in order to make informed clinical decisions about the use of a device or device type;
- The information may not be readily available to the affected target audience in the health care community; and
- The Center can make recommendations that will help the health care practitioner mitigate or avoid the risk. The recommendations reflect the current thinking of the Center on approaches for the health care practitioner to mitigate the risk associated with the problem.

In FY 04, the Center issued five Notifications as part of its information sharing with health care practitioners. All of the Notifications issued by CDRH can be found at <http://www.FDA.Gov/CDRH/safety.html>.

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Information Technology

Division Tracking System (DTS)

The primary purpose of DTS is to provide ODE and OIVD with a means to track the division level review process. Since the deployment of DTS, Division directors and branch chiefs have been able to track several details pertaining to the review process including the state of the review workflow. There are several reports available at the division, branch and office level that show progress towards MDUFMA goals, employee workload and other useful metrics. There is also a powerful custom report builder feature that allows users to generate their own custom queries on the data. These reports can be saved, printed, exported to PDF or exported to Excel.

During FY 04 the initial version of the Division Tracking System (DTS) was developed and deployed. The DTS development process began with a comprehensive requirements gathering phase during which several prototyping sessions were held with different groups of end users. The first release of DTS was deployed in February 2004. All existing data from the previous tracking system was converted to the new tracking system. During the remainder of the year, additional versions (updates) of the software were released. Version 1.4, the last version to be deployed in FY 04, provided the ability to enter and track Request for Designation (RFDs) for FDA's Office of Combination Products.

Image2000

Image2000, the CDRH system for storing electronic copies of device application submissions, was upgraded to provide additional capabilities for ODE and OIVD reviewers. The upgrades allowed users to:

- store documents in Portable Document Format (PDF), the Agency's standard;
- perform full text searching, copying or saving of documents; and
- print all or part of the submission.

In FY 04 CDRH began scanning over 2,200 boxes of past IDE and PMA paper submissions, making the data electronic, searchable and easily retrievable from the reviewer's desktop.

The Electronic Submissions Pilot was initiated with several manufacturers participating in the pilot program. The pilot allows industry to complete a 510(k) original submission using the CDRH eSubmissions application. CDRH received feedback from industry representatives and plans to roll out the software for production release in FY 06.

A Freedom of Information (FOI) Module was added to the Image2000 system. The modules allowed for on-line redactions for FOI requests of pre-market submissions.

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In addition, presentations on electronic submissions and document management were made to the Drug Information Association, AdvaMed, and at the FDA News's FDA Information Management Summit.

Turbo 510K (eSubmission)

In an effort to standardize the 510(k) submission, reduce premarket review effort and develop a better premarket/post market balance more in line with the TPLC regulatory concept, OIVD continued developing the Turbo 510(k) or eSubmission program. An eSubmission will guide the industry to submit only scientifically and administratively complete applications, making it easier to meet MDUFMA goals. In addition this program preserves institutional memory, enhances knowledge management and increases consistency of decision making regarding product clearances.

In FY 04, significant gains were made in the development of the Turbo 510(k) Stakeholder training provided suggestions for improvement. The Turbo 510(k) will be piloted on a voluntary basis in FY 05.

eRadHealth

CDRH continued the development of electronic radiological health submissions (eRad Health) to automate the review, analysis and management of the 19,000 radiological health safety product reports CDRH receives each year. We also initiated efforts to enhance system functionality by migrating over 300,000 records from the existing reporting database into the new database. The eRad Health project will enable CDRH to better monitor industry and the radiation-emitting electronic products by automating preparation, capture, and analysis of electronic product submission data.

Paperless Assignments for BIMO

In FY 04, we implemented a paperless inspection assignment process. The paperless assignment process helps to create over 300 Bioresearch Monitoring inspection assignments annually by electronic means, resulting in substantial cost savings for mail distribution and document storage and enhancing the efficiency of FDA's inspectional process.

CDRH IT Projects Under Development

In FY 04 CDRH IT continued developing IT tools necessary to carry out our mission, including:

- **eConsult** - Working with representation of all CDRH Offices, a Vision Document was written describing the role and broad expectations of eConsult. This system will coordinate and track consults requested by one Office of another Office.

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- **GMDN** - Working across several CDRH Offices, a Vision Document was created for GMDN.
- **eRoom** - Continue using the eRoom as collaborative tool and expanded the pilot to include various Program subjects/studies.
- **CFR** - Enhanced the Code of Federal Regulations database application to include final notices, a feature not available through the Government Printing Office but developed by CDRH and added to the FDA public website.

Industry Assistance

Members of the medical device industry are just as diverse as the products that they manufacture:

- there are approximately 18,000 manufacturers of medical devices worldwide;
- more than 70 percent of medical device manufacturers are small enterprises with fewer than 50 employees; and
- more than 40 percent of U.S. device firms also manufacture abroad.

This complexity and diversity present a challenge to FDA as a regulatory and public health agency. They also present a challenge to the medical device manufacturers who must comply with FDA regulations. Better communication between FDA and manufacturers opens the door for improved understanding, provides for a better working relationship, and results in quicker access to devices by the public.

Small Business Activities

FDA has instituted a number of activities aimed specifically at increasing communication with the small business community. In addition to Small Business Assistance Programs that reside in each of the five FDA regional offices, each Center in FDA has a special small business unit.

CDRH's small business division (<http://www.FDA.Gov/CDRH/industry/support/>) strives to:

- identify ways in which FDA requirements can protect and promote the public health without being unfair or unduly burdensome to small business;
- encourage greater participation by small firms in the regulatory process itself, especially at the early stage when comments are sought on proposals that impact on the device industry; and
- educate CDRH staff on the needs of medical device manufacturers and potential problems they face in meeting FDA's regulatory requirements.

It also serves as the lead within CDRH for the MDUFMA Small Business Determination (SBD), processing 626 SBD requests (570 were granted and 56 were denied) in FY 04.

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Other types of assistance provided to small businesses are similar to those that provided to other domestic and foreign manufacturers of medical devices. These services are discussed in more detail in the following pages.

Assisting Manufacturers

The most fundamental assistance that CDRH provides to manufacturers involves responding to individual inquiries, questions and concerns. We do this through several mechanisms, including:

- **Automated Call Center:** CDRH maintains a 24 hours per day automated call center, offering manufacturers the opportunity to speak directly to a device specialist, who can answer their questions and direct them to the needed information. We typically receive and respond to an average of 30,000 telephone inquiries per year.
- **E-mail:** All of our web pages for manufacturers, and many other CDRH web pages, include access to the small business division email account, dsmica@CDRH.fda.gov. We respond to over 25,000 email inquiries per year. In addition, we receive and respond to approximately 1,500 written/fax inquiries per year.
- **510(k) Status Program:** We assist manufacturers in determining the status of their pending premarket notification applications (510(k)). Requests for this service have decreased dramatically as CDRH eliminated the backlog of 510(k) applications. However, we still receive approximately 484 requests each year. The following link provides instructions on this program: http://www.FDA.Gov/CDRH/dsma/510_stat.html
- **Broadcast Fax:** CDRH uses an automated fax system to rapidly distribute important CDRH information to our industry. We also distribute information to stakeholder organizations such as AdvaMed, RAPS, and FDLI who then provide a multiplier effect.
- **Facts on Demand (FOD):** FOD is an automated answering system that allows requestors to access over 700 CDRH publications via the facsimile machine. Almost all of the documents available by FOD are more easily available from the CDRH webpage. However, stakeholders still use FOD to obtain publications. In FY 2004, approximately 2,500 publications were obtained through this system. We continue to maintain this system by adding new guidance documents as they become available and removing the outdated documents.
- **Publication Distribution:** CDRH's OCER is a warehouse to over 1,000 FDA publications. Although approximately 80% are accessible electronically, our stakeholders still request hardcopies. In FY 2004, approximately 83,000 publications were distributed either by hardcopy or on diskette.
- **Manufacturers Assistance Website:** Our website is a comprehensive source of information for manufacturers. It provides easy access to the services we offer, issues of interest to manufacturers and copies of manuals and guidance documents. The site <http://www.FDA.Gov/CDRH/industry/support/> received 32,000 hits in FY 2004.

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Device Advice Webpage

Early on, CDRH recognized both the advantages and the limitations of providing extensive information for manufacturers on our website. Often, just having “access” to information doesn’t make it easy to find a particular document. Further, while a person might find a particular document, he might not be aware of related documents or information. To address these concerns, we designed and implemented Device Advice (www.FDA.Gov/CDRH/devadvice/). This website has been a successful source of information and received 133,000 hits in FY 2004. With Device Advice, industry can determine:

- whether the product is a radiation-emitting electronic product, a medical device, both a radiation-emitting electronic product and a medical device, or neither a radiation-emitting electronic product nor a medical device;
- the FDA reporting requirements and standards that may apply for a radiation-emitting electronic product;
- the classification of the product, if it is a medical device;
- the process for obtaining appropriate clearance to market the medical device; and
- information on any other requirements that might apply to a product.

Device Advice can also be used as a resource linking to regulatory manuals, precedence correspondence, import/export requirements, CDRH databases and a complete index of the Code of Federal Regulations (Title 21 CFR).

CDRH device specialists launched the first version of Device Advice in 1998. Since then, it has consistently been one of the ten most used CDRH websites. In FY 2004, we modified topics to include the following information:

- **Updated user fee pages** - FY04 fees, small business reduction for 510k’s
 - 510k fee <http://www.FDA.Gov/CDRH/devadvice/314a.html>
 - PMA fee <http://www.FDA.Gov/CDRH/devadvice/pma/userfees.html>
- **Workshop page** - added fy04 workshops
 - <http://www.FDA.Gov/CDRH/dsma/workshop.html>
- **Third Party Inspections** – new page
 - <http://www.FDA.Gov/CDRH/ap-inspection/index.html>
- **Accredited Persons Inspection Program** – new page
 - <http://www.FDA.Gov/CDRH/ap-inspection/ap-inspection.html>

Workshops/Presentations

During FY 2004, CDRH partnered with other organizations in presenting 15 workshops for manufacturers. The workshops allow us to meet with manufacturers face to face and to exchange information on topics such as regulatory requirements, Quality Systems, and import and export requirements. Our partners in presenting the workshops included the following organizations:

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- Association for the Advancement of Medical Instrumentation (AAMI);
- Regulatory Affairs Professional Society (RAPS);
- AdvaMed; and
- Medical Design & Manufacturing (MD&M)

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CDRH Clinical Laboratory Improvement Amendments Activities

The Department of Health and Human Services delegated the authority to implement the Clinical Laboratory Improvement Amendments' (CLIA's) complexity categorization provisions, as they apply to commercially available tests, to FDA in a delegation published in the Federal Register on April 27, 2004. Implementing and interpreting CLIA's complexity categorization provisions involves activities necessary to determine whether laboratory tests will be categorized as waived, moderate complexity, or high complexity tests. Based on this new authority, CDRH's OIVD established quarterly tri-agency meetings with the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) to coordinate activities of the various agencies that affect aspects of the CLIA program that are delegated to each agency. Additionally, OIVD, with help from CDC, CMS and the HHS Advisory Committee for CLIA, began the process of clarifying what products satisfy CLIA.

Human Subject Protection

One of HHS's strategic goals is to enhance the capacity and productivity of the Nation's health science research enterprise by strengthening the mechanisms for ensuring the protection of human subjects and the integrity of the research process. To protect human subjects and the integrity of the research process, in FY 04 the Division of Bioresearch Monitoring's Research Misconduct program halted research associated with certain high risk investigational devices such as hip and knee implants for the elderly, devices for plugging holes in pediatric patients' hearts, lasers used for surgical procedures in the eye, coronary stents, ultrasound surgical devices for uterine fibroids, and diagnostic kits for infectious disease. Some of these actions are discussed in more detail below.

Application Integrity Policy

Application Integrity Policy is applied to firms that have engaged in wrongful acts that raise significant questions regarding data reliability or human subject protection in research or marketing applications submitted for review. CDRH stops substantive scientific review of pending applications and may ask the firm to withdraw any approved applications until violations have been satisfactorily corrected and procedures and controls that will prevent further recurrence of these violations have been implemented. In FY 04, CDRH placed three firms on FDA's Application Integrity Policy List. As a

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result, one firm withdrew six suspect applications for orthopedic prostheses; CDRH stopped another firm's research on a pediatric device; and CDRH suspended review of a pending application for an infectious disease diagnostic device.

Early Intervention Program

CDRH initiated a program that focused on real time inspections, those conducted during the research phase of an investigational device exemption (IDE), for active device research involving exploitable populations such as pediatric and physically challenged subjects, as well as studies involving novel or breakthrough technologies. Normally bioresearch monitoring inspections are done after the research has been conducted and the data is submitted to CDRH with a premarket approval application. Under this initiative, the inspection assignments are issued as the research is being conducted, so that adjustments can be made during the research rather than after, to help prevent improper research activities from harming patients and impeding the process for advancing medical technology.

Unapproved Pediatric Device Removed from the Market

In FY 04, CDRH stopped research on a pediatric device to treat a congenital heart defect when inspectional findings disclosed that the sponsoring firm had failed to report two deaths that occurred with the device before CDRH had approved it for use in research. CDRH also found that several physicians had implanted infants and children with the device without CDRH or institutional review board (IRB) approval and without informing the children's families that they had used an investigational device. While use of the unapproved device could negate the need for open heart surgery in some cases, not all of the clinical outcomes were positive. The investigation prompted the hospital's IRB to conduct their own internal investigation, resulting in dismissal of two participating doctors and a senior administrator, and termination of the research. Follow up inspection of the device manufacturer revealed other physicians who had been shipped the unapproved device. Appropriate CDRH regulatory and administrative response resulted in an unapproved device being removed from the market, and notification and follow-up for pediatric patients. Further research of this unapproved device will be conducted under a carefully designed, CDRH-IRB approved clinical trial.

Import Monitoring and Inspections

During FY 04, CDRH continued to enhance risk-based management of the import monitoring and inspection program in order to assure the safety of medical products manufactured for use by American consumers.

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Management of Inspection and Enforcement Actions

CDRH created and implemented a risk-based management program for inspection and enforcement actions which will improve the decisions CDRH makes in regulating and monitoring the medical device industry. The new program will impact how CDRH prioritizes inspections and identifies and prioritizes other types of regulatory activities, such as device recalls, that present the greatest risk to public health.

Risk Assessment Criteria Developed

As part of the new risk-based management program, CDRH used the ISO standards' definition of risk as a foundation in developing its risk assessment criteria. This definition shows risk to be a combination of the probability of occurrence of harm and the severity of that harm. Harm is a negative effect on a person or person's health due to an unsafe or ineffective device, reduction in a device's safety/effectiveness, clinical benefit, fitness for use, improper use, or quality. CDRH's new risk assessment criteria help focus our limited field resources on those medical devices and manufacturers that present the greatest risk to public health.

Work Planning Prioritization

CDRH developed a prioritization process proposal for work planning using Center-wide risk assessment criteria, and implemented an inclusive risk-based inspection work plan process. This process ensures that all Center program offices are afforded an opportunity to provide input into prioritizing special emphasis inspections;

Division of Risk Management Operations

The Division of Risk Management Operations was created within CDRH's Office of Compliance to focus more attention on risk management activities and support. The new division includes a Risk Management and Analysis Branch that focuses on collecting data from systems already available but not linked, analyzing and presenting findings that can be used in the risk-based decision making process. In addition, the Branch is responsible for monitoring program outcomes, analyzing current medical device compliance programs and identifying the need for more effective medical device compliance programs.

Reduced Inspection Delays

This fiscal year, we reduced premarket inspection delays, from 53% in FY03 to 15%, despite foreign inspection travel restrictions. This was achieved through improved communication and coordination with ORA management including reporting current status of inspection assignments for early intervention of problem areas, awareness of mandated timelines, and the assignment of PMA coordinators in the district offices.

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Inspections for Reprocessed SUDs

In FY 04 we inspected over 100 randomly identified U.S. hospitals to determine their compliance with the Quality System regulation for the reprocessing of single use devices. The inspections found no hospitals currently reprocessing SUDs.

Radiological Health

Radiological Health Consolidation

The CDRH Radiological Health Program reorganized effective September 30, 2004. Sixteen staff members, who conducted radiological health activities within the Office of Compliance, were reassigned to OCER. The Electronic Products Branch and the Diagnostic Devices Branch are now located within OCER's Division of Mammography Quality and Radiation Programs.

This reorganization was the outcome of a 2-year review of CDRH's Radiological Health Program. The review was summarized in a report from the facilitating contractor and a number of CDRH radiological health staff. The report indicated that the current problems of public health significance in the radiological health arena are largely problems of use (rather than problems with the equipment itself) and these problems are best addressed by emphasizing user and public education, a principal function of OCER. A core planning team has been charged with the task of developing a plan for the CDRH Radiological Health Program by mid FY 05.

Radiological Health Program Accomplishments

CDRH continued working with government security agencies and standards organizations to provide technical and regulatory consultation on equipment, standards, and research related to x-ray security screening devices.

In FY 04 we:

- Updated the "FDA Emergency Counterterrorism Preparedness and Response Plan for Radiation", identifying key personnel and processes for FDA to follow when responding to a national radiological emergency.
- Partnered with state-level radiological health agencies to communicate radiological health issues directly to the end-user. Worked closely with the National Evaluation of X-ray Trends (NEXT) program and the Conference of Radiation Control Program Directors (CRCPD) to monitor the radiation doses received by patients during diagnostic x-ray exams. Published a paper in Radiology on the 1995 NEXT Abdomen and Lumbosacral Spine survey.
- Conducted a two-week Diagnostic X-ray Inspectors Training Course for state and FDA inspectors. This course is the primary tool by which CDRH provides training to state inspectors participating in agreements with the Agency to conduct

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diagnostic x-ray field survey tests. The course allows the Agency to maintain an adequate number of qualified FDA and state x-ray inspectors in the field.

- Drafted proposed amendments to the Federal Laser Performance Standards 21 CFR 1040.10 and 1040.100, which adopt by reference and with national exceptions, the IEC laser standards (60825-1 and 60601-2-22) as the new Federal standard. The amendments move to create a single global regulatory environment for laser product manufacturers by reducing the regulatory burden on industry and updating the Federal standard to reflect current laser technology and bioeffects research.

Mammography Quality

The National Mammography Quality Assurance Advisory Committee

The National Mammography Quality Assurance Advisory Committee (NMQAAC) is a committee established by the Mammography Quality Standards Assurance Act (MQSA) to advise CDRH on the implementation of the MQSA program. A Committee meeting was held on April 19, 2004. During that meeting the Committee suggested several ways to streamline the MQSA inspection process and lessen the regulatory burden on mammography facilities. It also reviewed the issues facing MQSA with respect to the use of data compression algorithms and the digitization of film-screen mammograms.

MQSA Reauthorization

On October 25, 2004, President Bush signed H.R. 4555, "The Mammography Quality Standards Reauthorization Act of 2004", to amend the Public Health Service Act to revise and extend provisions relating to mammography quality standards. Provisions relating to the certification of mammography facilities were added, which codify existing certification practices. In addition, adjustments were made to the membership and frequency of the NMQAAC. Representatives from related industries will now serve as committee members, and the advisory committee meeting will now be required to meet once a year rather than twice a year. The reauthorization expires on September 30, 2007.

Additional Mammography Review Process (AMR)

An AMR is a review of clinical images and other relevant information to assure that the facility is in compliance with MQSA. CDRH has had preliminary discussions about AMRs internally and with approved accreditation bodies. We examined a number of issues specific to AMRs and Patient and Physician Notifications (PPNs) including:

- reasons for requesting AMRs;
 - procedures for performing AMRs (number of cases and number of reviewers);
 - criteria used to evaluate AMRs;
 - methods for evaluating the effectiveness of Corrective Action Plans and/or PPNs;
- and

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- role of medical outcomes and other evidence in the AMR/PPN process.

Digital Mammography

This new technology promises to enhance mammography by reducing the need for some women to have additional exposures while allowing interpreting physicians to quickly and easily manipulate the images. CDRH's Office of Device Evaluation (ODE) has approved the following Full Field Digital Mammography (FFDM) systems for commercial use:

- General Electric (GE) Senographe 2000D, January 2000
- Fischer SenoScan, September 2001
- Lorad Digital Breast Imager, March 2002
- Lorad Hologic Selenia FFDM System, October 2002
- Siemens Mammomat Novation DR Full Field Mammography (FFDM) System, August 2004.

Once approved, a facility must apply to become accredited by an FDA approved accreditation body. Currently, there are 778 FFDM units accredited at 566 facilities in the U.S. CDRH has approved the following Accreditation Bodies to accredit FFDM units:

American College of Radiology

- GE Senographe 2000D (approved 12/18/02; became effective 02/15/03)
- Fischer SenoScan (approved 07/24/03; became effective 08/15/03)
- Lorad Selenia (approved 09/05/03; became effective 09/15/03)
- GE Senographe DS Full Field Digital Mammography (FFDM) (approved 08/12/04; became effective 09/15/04)

State of Iowa

- GE Senographe 2000D (approved 08/28/03; became effective 10/01/03)
- Lorad Selenia (approved 08/28/03; became effective 10/01/03)

State of Texas

- GE Senographe DS Full Field Digital Mammography (FFDM) units within Texas (approved 08/12/04; became effective 09/15/04)
- Fischer Imaging SenoScan, GE Senographe 2000D and
- Lorad/Hologic Selenia Full Field Digital Mammography (FFDM) (approved and became effective on 05/21/04)

States as Certifiers (SAC)

The SAC program allows qualified states to assume certain key MQSA responsibilities. The program authorizes qualified states (currently Illinois and Iowa) to certify mammography facilities within their jurisdiction, to conduct annual inspections, and to

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enforce the MQSA quality standards under CDRH oversight. In May 2004, CDRH transitioned these SACs from the interim regulations to the final regulations.

Inspection Demonstration Program

Under the MQSA Reauthorization Act, Congress authorized FDA to undertake an inspection demonstration program (IDP) to assess the results of conducting some mammography inspections less frequently than annually. The purpose of the program is to evaluate whether selected mammography facilities can maintain the same level of quality without CDRH's current scrutiny through our annual inspections. In its final form, the IDP includes approximately 160 study group facilities and an equal number of controls in 14 States or other governmental jurisdictions that have agreed not to inspect these facilities under their own authority during the study period. The first half of these facilities were selected and notified in November 2001 and the second half were selected and notified in May 2002. Each facility was randomly selected from a set of eligible facilities on a jurisdiction-by-jurisdiction basis. The facilities must have had a clean inspection history for the last two inspections to be eligible. The facilities in the study group underwent biennial inspections during the demonstration program, during which inspectors looked at the same areas as the current annual inspections, except that they reviewed for the entire period since the last inspection date. All study group facilities were inspected by the end of August 2004. A report on the program, "The Effect of Reducing Inspection Frequency," was published on the MQSA website, Mammography Matters, on January 12, 2005. The report is available at <http://www.FDA.Gov/CDRH/mammography/index.html>.

MQSA Compliance Activities

CDRH conducted inspections of mammography facilities and found that more than 97% of the facilities met the MQSA inspection standards, with only 2% of the facilities showing Level 1 (most serious) problems.

In addition we:

- Incorporated MQSA national facility inspection data on the MQSA Facility Scorecard web page. This web page provides information about facility performance on MQSA standards, gives facilities the opportunity to compare themselves to the rest of the nation, and provides a mechanism for facilities to contact CDRH regarding the scorecard and other MQSA issues.
- Implemented a new enforcement strategy that addresses how facilities should respond to serious (Level 1) inspection observations, and what follow-up actions CDRH may take if facilities do not correct the problems.
- Issued a talk paper to notify patients and their referring physicians regarding a serious risk to human health as a result of mammograms performed at a mammography facility in Florida. The facility had refused to directly notify patients.

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- Formed the Repeat Observations Working Group as a recommendation from the Device Field Committee to explore new approaches to deal with facilities with repeated inspection observations over several inspections.

Research and Technology

CDRH X-ray Calibration Laboratory

Through the operation of the CDRH X-ray Calibration Laboratory, CDRH provides the necessary traceability to national standards for instruments used by FDA and state inspectors to measure x-ray exposures from CDRH-regulated products. The calibration laboratory is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) and complies with ISO Standard 17025.

CDRH OSEL's staff performed a total of 1393 accredited calibrations of radiation probes by irradiation in reference x-ray fields. CDRH also performed 688 electrical calibrations of radiation monitors and 142 calibrations of non-invasive kVp meters. Of the radiation probe calibrations, 67% were for FDA-owned instruments, 31% for State-owned instruments, and 2% for other federal agencies. The work output was distributed by program as follows: approximately 68% of the calibrated instruments were designated for the Radiation Control for Health and Safety Act (RCHSA) program, 25% for The Mammography Quality Standards Act (MQSA) program, 3% for other federal agencies, and 3% for internal laboratory use. In addition, staff performed an unspecified number of tests of Geiger-Mueller survey instruments and light meter calibrations.

CDRH Ionizing Radiation Measurements Laboratory (IRML)

In FY 04, CDRH's Ionizing Radiation Measurements Laboratory (IRML) in OSEL invested over \$200,000 on equipment and supplies for the RCHSA and MQSA field programs and to keep the calibration laboratory updated and traceable. The IRML staff researched instrumentation and equipment for x-ray testing; performed laboratory evaluations; prepared specifications and purchase requisitions; performed acceptance testing; distributed instruments based on inspection load, contracts, or agreements; maintained a database of instrument usage, repair, and calibration histories; repaired or arranged for repairs for all field instruments as needed; responded to inquiries regarding ionizing radiation measurements and instruments performance; and worked with OCER personnel on new test procedures. In addition, the laboratory staff made significant updates to the calibration laboratory's automation systems, including fabrication of new electro-mechanical controllers and the near completion of new Labview software to control the calibration process.

IRML continues to contribute to the Center's effort regarding the safety of x-ray security screening systems and actively participates in discussions with other agencies, users, and manufacturers on the need for new radiation safety standards. CDRH was instrumental in

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the April 2004 formation of Task Group N43.16. The group will develop a new ANSI standard on cargo screening systems. Currently, CDRH is facilitating the exchange of information by the different security agencies through the Interagency Steering Committee on Radiation Standards.

Wireless Technology EMC for Medical Devices

FY 04 Program Accomplishments

- Performed electromagnetic compatibility (EMC) testing on wireless medical telemetry at three local hospitals to see how mobile radio transmitters might affect patient the older mobile radio frequencies information. The American Society for Healthcare Engineering (ASHE) located the hospitals, and ASHE and staff from the FCC engineering laboratory participated. This work is helping to convince hospitals to migrate to the protected WMTS frequencies
- Developed computer modeling techniques for evaluating EMC between realistically-shaped medical implants and antennas. Validated these with laboratory experiments. Presented findings at a technical conference and published them in conference proceedings.
- Developed unique, anatomically correct computer simulation models for pregnant women and children for human exposure studies with walk through (WTMD) and hand-held (HHMD) metal detectors. Formed collaboration with Dr. Ji Chen, University of Houston working under a National Science Foundation grant to develop an equivalent source model for human exposure to these security systems. Gathered data from emissions measurements on 3 WTMDs Submitted abstracts for presentations at the BEMS conference.
- Performed testing and computer simulations with Bluetooth and IEEE 802.11 wireless technology that revealed significant coexistence and data latency (e.g., transmission slowdown and drop-outs) concerns. Observed that the widely used 802.11b technology can be adversely affected by Bluetooth and other in-band signals. Computer simulations confirmed these concerns, but issues about the interpretation of the computer simulations limit the use of the present tool.
- Completed IAG project with the U.S. Army Telemedicine and Advanced Technology Research Center (TATRC) to study EMC and wireless technology among medical devices and wirelessly enabled PDAs.
- Developed simulation tool for Bluetooth and IEEE 802.11b wireless technology to study data loss and corruption, latency, through-put, and coexistence with other wireless signals. A project report was presented to TATRC.
- Performed the first international comparison of cell phone SAR computations and measurements with SAM (standard anthropomorphic man) phantoms under CRADA with the Mobile Manufacturers Forum (MMF). Over 15,000 data points from 14 national and international universities, test laboratories, and manufacturers were analyzed. Findings suggest that the SAM phantom produces higher SAR values than anatomically accurate computer models. This work is the first study to reveal the variations in SAR computations across several independent institutions for the same SAM phantom.

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- Completed magnetic field emissions measurements on 30 HHMDs creating unique, independent data about these security systems. Tested implanted cardiac pacemakers, implanted cardiac defibrillators, implanted neurostimulators, partially implanted drug infusion device for EMC with these security systems. Discovered one HHMD emits significantly higher fields (more than 600 A/m compared to typically up to 30 A/m from other HHMDs) that can affect pacemaker and neurostimulator output and a personnel drug infusion device. Reported preliminary findings to FAA/TSA under the IAG.

Standards Development

FY 04 Program Accomplishments

- Established a new standards management database for the Intranet to facilitate Center-wide knowledge of our standards activities and our liaison representatives.
- Established liaison representative training module that will be required annually.
- Noted the largest recognition of standards since FDAMA.
- Implemented the new guidance initiative and OSEL details to ODE to facilitate the development of guidances.
- Established the Implantable Middle Ear Hearing Devices standard activity – from conceptual meetings to a draft ASTM standard.

Workshop on Drug-Diagnostics Translational Research

The new field of pharmacogenetic research will enable pharmaceutical companies to develop drug treatments that precisely target the needs of particular patient populations. By linking drug treatments to diagnostic tests that can accurately identify appropriate receptive patients, pharmaceutical companies aim to decrease drug adverse events, increase drug response rates, and ultimately save healthcare dollars. On July 29, 2004 CDRH initiated a national workshop on the co-development of drugs and diagnostics. The purpose of this workshop was to allow for stakeholders to provide in a public venue scientific suggestions and concerns about CDRH regulatory practices in this important and growing new area. Over 300 members of CDRH, drug companies and diagnostic companies attended. The proceedings of this conference are being used by CDRH to develop guidance to ensure that this type of research translates in a rapid and cost-effective manner to new joint products that can quickly enter the medical marketplace.

Collaboration with Centers for Disease Control and Prevention

On June 28, 2004 CDRH published a letter to manufacturers of antimicrobial susceptibility tests pointing out a serious problem had emerged. It had been observed that because of mutation in an important disease causing bacteria (*Staphylococcus aureus*), automated test systems could not detect if they were sensitive or resistant to standard treatment using the antibiotic Vancomycin. This test failure had the potential to cause errors in treatment with serious consequences. Working with Centers for Disease Control and Prevention, CDRH developed recommendations for manual alternative tests

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to fill the gap, developed a procedure for companies to test modified systems to see if automated test systems could be adjusted to resolve this problem, and issued wide public health notice of this problem.

Transmissible Spongiform Encephalopathy (TSE): Evaluation of Prion Decontamination Procedures

Creutzfeldt-Jakob disease (CJD,) a human form of transmissible spongiform encephalopathy (TSE) that occurs worldwide, is a rapidly progressive, invariably fatal neurodegenerative disorder believed to be caused by a prion protein. The World Health Organization has developed infection control guidelines for CJD that include the destruction of heat-resistant surgical instruments that come in contact with high-infectivity tissues. Since this safest and most unambiguous method may not be practical or cost effective, CDRH scientists examined the effects of using aggressive decontamination techniques on the instruments instead. The study results, including aggressive decontamination techniques that can be used as alternatives to the destruction of heat-resistant surgical instruments that come in contact with high-infectivity tissues, were published in the peer-reviewed scientific literature. A full report on this study is available on the Centers for Disease Control and Prevention (CDC) website. (See http://www.cdc.gov/ncidod/diseases/cjd/cjd_inf_ctrl_qa.htm). CDRH's data are the basis of the CDC website's cautionary warnings on TSE.

Guidance Development

CDRH worked with the Office of General Counsel and the Office of Policy Regulation editorial staff to review and revise all boilerplate templates for all guidance documents. These templates are available to the Center Good Guidance Practices (GGP) office representatives on the Center's website at <http://www.CDRH.fda.gov/LAWS/GGP/default.htm>.

The Center published a great number of final and draft guidance documents. The next two sections contain comprehensive lists of final guidance documents adopted and draft guidance documents published in FY 04.

Final Guidance Documents Adopted

- Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Sirolimus Test Systems
- Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications
- Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan

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- Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Dental Noble Metal Alloys
- Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Dental Base Metal Alloys
- FY 05 MDUFMA Small Business Qualification Worksheet and Certification - Guidance for Industry and FDA
- Guidance for Industry: FDA Export Certificates
- A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff
- 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
- User Fees and Refunds for Premarket Notification Submissions (510(k)s) - Guidance for Industry and FDA Staff
- FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment - Guidance for Industry and FDA Staff
- Premarket Assessment of Pediatric Medical Devices - Guidance for Industry and FDA Staff
- Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff
- Immunomagnetic Circulating Cancer Cell Selection and Enumeration System - Class II Special Controls Guidance Document - Guidance for Industry and FDA Staff
- Spinal System 510(k)s - Guidance for Industry and FDA Staff
- Premarket Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove - Guidance for Industry and FDA Staff
- Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems - Guidance for Industry and FDA Staff
- Surgical Masks - Premarket Notification [510(k)] Submissions; Guidance for Industry and FDA
- Vocal Fold Medialization Devices - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff
- Cyanoacrylate Tissue Adhesive for the Topical Approximation of Skin - Premarket Approval Applications (PMAs) - Guidance for Industry and FDA Staff
- Consumer-Directed Broadcast Advertising of Restricted Devices
- Clinical Study Designs for Percutaneous Catheter Ablation for Treatment of Atrial Fibrillation - Guidance for Industry and FDA Staff
- Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff
- Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA Staff
- Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices - Guidance for Industry and FDA Staff

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- Expedited Review of Premarket Submissions for Devices - Guidance for Industry and FDA Staff
- Bundling Multiple Devices or Multiple Indications in a Single Submission - Guidance for Industry and FDA Staff
- User Fees and Refunds for Premarket Approval Applications - Guidance for Industry and FDA Staff
- Premarket Approval Application Modular Review - Guidance for Industry and FDA Staff
- Class II Special Controls Guidance Document: Endotoxin Assay
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus
- Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm
- The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System # 8
- FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Performance Assessment - Guidance for Industry and FDA Staff

Draft Guidance Documents for Comment Purposes Only

- Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus
- Draft Guidance for Industry and Food and Drug Administration Staff; Hospital Bed System Dimensional Guidance to Reduce Entrapment
- Draft Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Dental Bone Grafting Material
- Requests for Inspection by an Accredited Person Under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002 - Draft Guidance for Industry, FDA Staff, and FDA-Accredited Third-Party

Part 5. Protecting the Homeland -- Counter Terrorism (CDRH Strategic Goal: Public Health Impact)

Emergency Preparedness

Detection of a Biothreat Pathogen with First Anthrax Quick Elisa Test

In June 2004, CDRH cleared the first Anthrax Quick Elisa test. The test, manufactured by Immunetics Inc. of Boston, detects antibodies produced by a *Bacillus anthracis* infection in less than one hour and is an important new diagnostic tool in the ability of U.S. laboratories to address a serious potential biothreat pathogen. Before CDRH approval, very few laboratories other than the Centers for Disease Control and Prevention and the U.S. Army had the ability to test blood for antibodies to anthrax. The new test is available for use in state and private laboratories. This clearance was the result of a collaborative interaction between CDRH, Centers for Disease Control and Prevention and a commercial partner, showing how such cooperative work can lead to approval of diagnostic tests for biothreat agents and emerging infectious diseases.

Process to Identify Shortages

CDRH developed a new, more responsive process of identifying potential device shortages and the responsibilities for managing the shortages during public health emergencies/terrorist events.

Emergency Shortages Data Collection System

CDRH developed an improved Emergency Shortages Data Collection System that allows quick identification of device manufacturers and available inventories. This is intended to facilitate identifying potential shortages in medical and *in vitro* diagnostic devices that may be needed by emergency healthcare personnel in the acute phase of an emergency/disaster. This data is handled as non-releasable, confidential commercial information.

Emergency Preparedness SOPs

CDRH developed standard operating procedures to sustain standardization of activities relevant to successful emergency preparedness, such as SOPs for handling and storing Top Secret and Secret documents.

Part 5. Protecting the Homeland

Emergency Response Coordinating Workgroup

CDRH formed the Emergency Response Coordinating Workgroup (ERCW), which includes the core emergency personnel involved in initial response to a call for action in an emergency. ERCW responsibilities cover revising and updating the Emergency and Disaster Operations Procedures, writing new SOPs to update and improve response times, trouble-shooting on issues related to emergency exercises, and developing after action reports (AAR) to clarify issues after an exercise.

COOP Readiness

CDRH updated the Continuation of Operations Plans (COOP) and conducted quarterly exercises to improve readiness of all COOP and communication systems in CDRH.

Response Plans for Radiological Emergencies

CDRH participated in interagency working groups focused on developing protective action guides following Radiological Dispersal Devices and Improvised Nuclear Devices events. In FY 04, we finalized the Emergency Preparedness and Radiological Health Response plan, identified essential emergency personnel, and established a Corporate Communications Center to conduct emergency operations related to medical devices and radiological health products.

Part 6. Improving Business Practices (CDRH Strategic Goals: Total Product Life Cycle and Magnet for Excellence)

Managing Priorities

Strategic Planning and Organizational Scorecards

In FY 04, CDRH implemented organizational scorecards for the Center and for each Office. Organizational scorecards, a CDRH Strategic Plan Phase II initiative, are intended to align work processes in each Office by measuring performance in key result areas. Continued monitoring enables the Center to take corrective action, if needed.

Implementation of MDUFMA presents major performance management challenges. FY 04 organizational scorecards included MDUFMA indicators. Quarterly scorecard reports provided important assistance and information for the Center's quarterly FY 04 MDUFMA reports.

The CDRH Measurement Team reports performance on key indicators regularly throughout the year. During FY 04, scorecard data was quarterly reported on twelve active indicators in the Center scorecard. Third and fourth FY 04 quarter CDRH scorecard reports are posted on the strategic planning site, <http://www.FDA.Gov/CDRH/strategic/>.

CDRH Alignment with Department Goals and President Management Agenda

The President's Management Agenda and the Department's One HHS Management Objectives have given departments and agencies the mandate to seek out ways to improve the public health while increasing the linkage between dollars and performance. The Center for Devices and Radiological Health has responded to this by evaluating and ensuring alignment between Center goals and the priorities of the Commissioner, Secretary and the President. This included efforts to identify and communicate the Center's role in presidential, department, and agency initiatives, which resulted in higher scores on the OMB PART Evaluation, exceptional ratings on agency yearly organizational assessment with the department, and positive performance evaluations with the Commissioner. It has also resulted in greater understanding among Center employees of agency and department initiatives.

CDRH regularly reviews its goals to ensure alignment with the following initiatives:

- Presidents Management Agenda
<http://www.whitehouse.gov/omb/budget/fy2002/mgmt> and
<http://www.results.gov/>

Part 6. Improving Business Practices

- Government Performance & Results Act-
<http://www.FDA.Gov/ope/fy04plan/2004pp-mainpage.html>
- HHS Strategic Plan - <http://aspe.hhs.gov/hhsplan/>
- OMB Long Term Outcome Goals -
<http://www.FDA.Gov/ope/fy04plan/2004pp-mainpage.html>
- FDA Strategic Plan - <http://www.FDA.Gov/oc/mcclellan/strategic.html> and
<http://www.FDA.Gov/oc/initiatives/reports/priorities2004.html>
- CDRH Strategic Plan - <http://www.CDRH.fda.gov/strategic/default.htm>

For more information on HHS, FDA, and CDRH Program Initiatives, please visit the following link: <http://www.FDA.Gov/CDRH/annual/fy2003/program.html>.

CDRH Communication Plan

In FY 04, a Communication Plan was developed and piloted in CDRH. The Plan outlines processes to:

- plan, prioritize, and budget for CDRH communication activities;
- help employees communicate across CDRH and share expertise on outreach projects; and
- provide consistent and coordinated messages to the public.

Magnet for Excellence

CDRH continued to build effective and efficient operations and a highly skilled and diverse workforce needed to carry out the agency's goal of more effective regulation through a stronger workforce.

Medical Device Fellowship Program

The CDRH Medical Device Fellowship Program (MDFP) provides opportunities for health professionals to participate in the regulatory process for medical devices. MDFP participants are experts in their fields. They perform a variety of duties in CDRH, including:

- reviewing and consulting on premarket submissions, especially in specialized areas, such as vascular grafts and stents, spinal implants, software, etc.;
- addressing human factors issues;
- performing analysis of device failure modes; and
- developing standards and guidance.

In FY 04 the MDFP had 64 participants. Information about MDFP is available at <http://www.FDA.Gov/CDRH/mdfp/index.html>.

Part 6. Improving Business Practices

Mentoring for Excellence Program

CDRH completed the “Mentoring for Excellence Program” pilot for new managers. The program is intended to develop management competencies which top managers have identified as crucial in CDRH’s culture. The results are being reviewed and CDRH is exploring ways to integrate this tool into the diverse leadership enhancing programs offered within the Center.

Continuing Science Education Program

CDRH created the Continuing Science Education Program, or CSEP, which offers joint educational programs with selected colleges and universities. CSEP has two different programs for targeted audiences: the Basic Science Education Program, also known as BSEP, and the Science Leadership Education Program, known as SLEP. These programs are designed to encourage continual learning and provide employees with an opportunity to enhance their overall scientific knowledge.

Competency Model

The development of a Competency Model that will identify the essential core, science, and functional or job category competencies for CDRH employees was initiated. The model is intended to guide employees’ professional development and ultimately enhance job performance and meet organizational goals.



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