CDRH: Ensuring the safety and effectiveness of medical devices and the safety of radiation emitting products

The Food and Drug Administration's Center for Devices and Radiological Health (CDRH) helps ensure that medical devices are safe and effective, and that products emitting radiation such as microwave ovens do not expose people to harmful levels. The Center also administers a nationwide inspection and certification program for mammography facilities to help ensure high-quality breast imaging.

In 2005, CDRH promoted and protected health by evaluating and approving highly advanced new devices, and by monitoring the performance of devices already on the market and taking corrective action as needed.

NEW PRODUCT APPROVALS

CDRH approved 38 Premarket Approval Applications (PMAs) for medical devices that have no precedents in the United States, and cleared 2,617 510(k) submissions for products whose technologies have prior use and are well-understood. The most innovative products approved in 2005 included

- DuraSeal Dural Sealant System, the first approved material for sealing leaks in the dura mater covering of the brain
- Invader UGT1A1 Molecular Assay, the first DNA-based test for providing genetic information to help physicians make personalized treatment decisions
- VeriChip Implantable RF Transponder System, an implantable chip for maintaining the patient's medical data
- Syncardia Temporary CardioWest Total Artificial Heart, a device for patients at risk of imminent death from heart failure while awaiting a heart transplant
- CoAxia NeuroFlo Catheter, a device to treat insufficient blood flow to the brain, was approved under a special program for addressing rare but serious medical problems.

CDRH Workload: Number and Types of Major Submissions Received for Fiscal Year 2000 to Fiscal Year 2004

Type of Submission	2000	2001	2002	2003	2004
Original PMAs	67	71	49	54	51
PMA Supplements	546	641	645	666	635
Original IDEs	311	284	312	242	226
IDE Amendments	240	206	252	216	167
IDE Supplements	4388	4811	4724	4815	4312
510(k)	4202	4248	4320	4247	3635
Original HDE	11	5	5	10	9
HDE Supplements	10	16	16	29	29

Source: FDA Office of Device Evaluation Annual Report, Fiscal Year 2004

PATIENT PROTECTIONS

CDRH took numerous measures to strengthen patient protection and to improve medical outcomes involving the use of approved devices. Here are some of the key accomplishments in 2005:

- Improved problem detection and management: CDRH worked with manufacturers to design better postmarket clinical studies that are required for approval of a PMA; analyzed and responded to more than 180,000 reported medical device adverse events; began developing an electronic system for faster processing of adverse event reports; assessed the current post-market safety program; and continued working with MedSun, a national network of 350 health care facilities trained to recognize and rapidly report device problems.
- Better risk communication: CDRH increased access to information on regulated products and health issues on its Web sites, in newsletters, through increased outreach efforts, and through internal operational initiatives. For example, CDRH co-sponsored a conference on implantable cardioverter defibrillators and pacemakers, maintained a medical device safety Web site, and produced a monthly video news show for health care professionals called "FDA Patient Safety News."
- Research for patient safety: Among other patient safety-oriented projects, CDRH investigated the improvement of the mechanical strength of vertebrae after injections with bone glue, the most common treatment for compression fractures that affect one-fourth of all women over age 50. The center also measured the potential health effects of hand-held and walk-through security systems, cellular telephones, and hand-held computers, and examined the possible effects of MRI machines on implanted devices.

OVERSIGHT OF PRODUCT QUALITY

In fiscal year 2005 (Jan. 10, 2004, to Sept. 9, 2005), CDRH issued 437 recalls of products that did not measure up to the required standards of safety or quality. Some highlights of these actions follow:

- Seizure of Baxter Healthcare Corp. infusion pumps: FDA inspections showed the firm had continually failed to follow medical device manufacturing controls. Before the seizure, the infusion pumps were recalled because they could shut down while delivering critical medications to patients.
- Recall of Abbott Diabetes Care blood glucose meters: FDA investigation of reported problems found that the blood glucose meter, if dropped or during battery replacement, could inadvertently switch the glucose readings from the U.S. to the foreign standard. Misreading the results could result in dangerously false glucose readings.

In addition, CDRH's Radiological Health program provided crucial expertise for the review and approval of radiation treatment and therapy systems, prevention of excessive radiation exposures from diagnostic examinations such as fluoroscopy, and monitoring and evaluation of radiation-emitting security screening devices.