



Better Health Care with Quality Medical Devices: FDA on the Cutting Edge of Device Technology

More than 20,000 firms worldwide produce over 80,000 brands and models of medical devices for the U.S. market, ranging from contact lenses and blood sugar monitors to implanted hip joints and heart valves. The FDA's **Center for Devices and Radiological Health (CDRH)** makes sure that new medical devices are **safe and effective** before they are marketed. Many of these devices are the first of a kind, such as a robotic arm that can operate a variety of surgical tools with tremendous precision. Other high-tech devices are designed to prevent, diagnose or treat cancer, heart disease, impaired vision and hearing, and other health problems. The center also monitors devices throughout the product life cycle, including a nationwide postmarket surveillance system. And it assures that **radiation-emitting products**, such as microwave ovens, TV sets, cell phones, and laser products meet radiation safety standards.

The size of the CDRH workload is reflected in its performance statistics for 2001:

3,507 new products received marketing clearance, including 29 devices representing breakthrough technologies; 1,098 ongoing device trials were monitored; and 216 new clinical studies to test the safety and effectiveness of experimental devices in humans were

Advances in Medical Device Technology

CDRH's approvals in 2001 included numerous state-of-the-art medical devices, such as:

- the first implanted pacemaker that includes a tiny transmitter that automatically transmits data on the patient's heart condition to the physician
- a vest-like device for patients who cannot have an implanted defibrillator and are at risk of dying from heart attack; the device senses heart malfunction and automatically delivers an electrical shock to restore normal heart rhythm
- a wristwatch-like device for diabetics that automatically checks the wearer's glucose level every 20 minutes and sounds an alarm if it is dangerously high
- an inflatable device that is surgically placed around the upper stomach of greatly overweight patients who cannot lose weight by dieting and are at serious risk for weight-associated serious diseases, such as hypertension; the device limits their food consumption and creates an earlier feeling of fullness
- a swallowable capsule with tiny camera that snaps pictures as it moves through the small intestine; the device helps detect bleeding and other abnormalities that are reachable by endoscopy.

approved.

Although its workload is rapidly increasing, CDRH has streamlined its processes and reduced the average review time for novel and high-risk medical devices, which offer the greatest potential health benefits to patients. Between 1995 and 2000, approval times for these products declined from 26 months to 12 months.

In the near future, CDRH will be challenged to resolve complex issues connected with emerging technological and demographic developments, including:

- Diagnosis and treatment options related to the **human genome project**
- **Radiation safety** issues, including those associated with new medical imaging technologies
- **Breakthrough devices** using artificial intelligence, nanotechnology and robotics
- Special needs of our **aging population** for prosthetics, cardiac interventions, and home health care.

For more information, please call CDRH at 301-443-4690, or visit the FDA Web site at www.fda.gov/cdrh.