
Classification and evaluation of medical devices

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Abstract

Medical devices and medical disposables contribute significantly to the quality and effectiveness of the health care system. It is necessary to commit scientifically sound regulatory environment that will provide consumers with the best medical care. This includes continued services to small manufacturers, readily available guidance on FDA requirements, predictable and reasonable response times on applications for marketing, and equitable enforcement. But in the public interest, this commitment to the industry must be coupled with a reciprocal commitment: that medical device firms will meet high standards in the design, manufacture, and evaluation of their products. The protections afforded our consumer, and the benefits provided the medical device industry, cannot be underestimated.

Key words: medical devices, classification, manufacture, evaluation

Introduction

Medical devices are an extraordinarily heterogeneous category of products. The term "medical device" includes technologically simple articles such as hypodermic syringes and blood bags. On the other end of the spectrum are highly sophisticated articles such as pacemakers, surgical lasers, implantable pumps, and vascular grafts.

Medical devices and medical disposables contribute significantly to the quality and effectiveness of the health care system. Medical devices range from wound dressings to artificial hearts, designed to support life in many end-stage cardiac patients. The Food and Drug Administration (FDA) estimates that some 2700 medical devices and over 1500 medical disposables are used yearly. Biomaterials represent the fundamental reason for this impressive performance. In the early 1930s the only "biomaterials" were wood, glass, and metals. These were used mostly in surgical instruments, paracorporeal devices, and disposable products. The advent of synthetic polymers changed the entire character of health care delivery. Polymers originally designed for commercial applications were adapted for implantable prostheses, thus opening the way for pacemakers, vascular grafts, synthetic wound dressings that mimic intact human skin, and a variety of artificial organs (1).

Classification

FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements which apply to them are:

Class I devices (general controls) are intended primarily for applications that pose no potential risk to health, and thus can be adequately regulated without imposing standards or the need for premarket review. This category provides a broad general control. It requires that manufacturers register these devices with the FDA, provide a listing of products, maintain adequate reports, and comply with Good Manufacturing Practices (GMPs). Examples include stethoscopes, periodontic syringes, nebulizers, vaginal insufflators.

Class II devices (performance standards) are applicable when general controls are not adequate to assure the safety and effectiveness of a device, based on the potential risk to health posed by it. To classify a device in the Class II category, the FDA must find that enough data are available on which to base adequate performance standards that would control the safety and effectiveness of these devices. Examples include diagnostic catheters, electrocardiographs, wound dressings, percutaneous catheters, gastrointestinal irrigation systems.

Class III devices (premarket approval) include "critical devices," that is, life-supporting and life-sustaining devices, unless adequate justification is given for classification in another category. After 1976, Class III contained devices that are not sufficiently similar to pre-1976 devices, and devices that were regulated as new drugs before 1976. Examples include bronchial tubes, ventilators, vascular grafts, pacemakers, cardiopulmonary bypass, surgical meshes, and others.

In the past, medical devices, for the most part, were simple instruments such as stethoscopes and scalpels in which defects would be readily apparent. The technology boom after World War II, greatly increased the number and complexity of medical devices, including landmark products such as heart-lung machines and dialysis equipment.

According to the technical definition, a "device" is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body and which does not achieve its primary intended purposes through chemical action and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

As this definition suggests, many different types of products are properly regulated as medical devices. Medical devices include over 100,000 products in more than 1,700 categories. These range from simple everyday articles such as thermometers, tongue depressors, and heating pads, to the more complex devices such as pacemakers, intrauterine devices, fetal stents and kidney dialysis machines.

Although some of the earliest medical devices (e.g. bandages) have retained their same basic form and function, the complexity and use of medical devices have increased exponentially over the past sixty years. Patient care has improved dramatically as a result of these changes. The following examples illustrate advances that have been made in medical technology in just the last few years:

- heart defibrillators have progressed from large, bulky external pumps to small external machines to totally implantable devices;
- surgical tools enable to operate on a fetus in utero;
- coronary artery disease that once required open heart surgery has been largely replaced by less invasive techniques such as balloon angioplasty, insertion of cardiovascular stents, laser ablation of plaque and minimally invasive surgery;
- devices that are more sophisticated, more dependable and more convenient.
- "artificial" skin for burn victims is now available.
- many major surgical procedures (e.g., removal of the gallbladder) have been replaced with laproscopic procedures that require only small incisions. This "revolution" alone has dramatically reduced hospital stays and recuperation is much faster.
- new devices have been developed to do needle biopsy of breast abnormalities without general anesthesia or major surgery;
- many diagnostic devices now can be used at home-e.g., testing for blood clotting, pregnancy, cholesterol, glucose, genetic diseases;
- improvements to anesthesia systems have reduced risks to patients several-fold.
- new imaging systems (PET and MRI) provide a

dramatic improvement in image quality, information, content and analysis.

- cemented joint replacements for hips have given way to better functioning, more durable replacements, not just for hip problems but for nearly every joint in the body.

FDA has also approved several breakthrough devices:

- the Thoratec ventricular assist device system, for example, is a pump that assists the heart in patients who are waiting for a heart transplant and are at imminent risk of dying before a donor heart is available;
- the Ultramark high definition ultrasound system is a first-of-a-kind device to aid the physician in differentiating benign from malignant breast lesions;
- the PAPNET testing system is an aid in re-screening Pap smears previously reported as negative.

As diverse as medical devices are, so are the range and complexity of problems that can arise from their use.

These problems include:

- mechanical failure,
- faulty design,
- poor manufacturing quality,
- adverse effects of materials implanted in the body,
- improper maintenance/specifications,
- user error,
- compromised sterility/shelf life and
- electromagnetic interference among devices.

Examples of injuries resulting from use of medical devices include:

- bone disintegration caused by the material used in temporomandibular jaw implants;
- patient deaths caused by fractures in implanted artificial heart valves; and
- electrocution of babies when apnea monitor leads were mistakenly plugged into wall outlets.

The 1938 Act initially charged FDA with removing adulterated or misbranded medical devices from the market. It did not give the Agency the authority to review medical devices before entering the market. Changes were made in the Act in 1976 after a commission determined that more than 700 deaths and 10,000 injuries were associated with medical devices. After concluding that the Act did not provide sufficient authority for the FDA adequately to protect the public health with respect to medical devices, the Medical Device Amendments of 1976 were passed (1976 Amendments) (2).

The 1976 Amendments provided several mechanisms to achieve this goal, including classification of medical devices, device listing, establishment registration, adherence to Good Manufacturing Practices (GMPs), and extensive control over market introduction of medical devices. The Safe Medical Devices Act of 1990 (3) and the Medical Device Amendments of 1992 (4) revised and expanded the 1976 Act.

The Agency carries out its medical device responsibilities by:

- evaluating new products before they are marketed for conformance to requisite design, engineering bench tests, and, as needed, data from animal trials or clinical trials in patients;
- assuring quality systems are in place in the device manufacturing plants-through inspection and enforcement activities; and,
- collecting and monitoring adverse effects from marketed products and investigations, and taking action, when necessary, to prevent injury or death;

The process provides for orderly development of new devices starting with bench and animal tests, moving next through scientifically sound clinical investigations, and, only after independent review of the results, approval for marketing.

This system has three goals:

- (1) to screen out bad ideas and products that are unsafe or don't produce a benefit;
- (2) to provide early feedback in order to detect and fix design or manufacturing flaws; and
- (3) to give doctors and patients an accurate interpretable experience from which to determine in whom to use a device, what to expect from its use, and how to avoid a prolonged learning curve using it (so that patients benefit).

Evaluating new devices before they are marketed

Because of the diverse nature of devices and the device industry, it is necessary to have a product approval system with special characteristics. In the USA there is a classification system of products based on the degree of risk and the need for information on use of the device in patients.

Devices on the market at the time the original law was passed were assigned to one of three "classes." Those presenting the least risk, such as elastic bandages, were placed in Class I and subject to "general controls." General controls include registration and listing, prohibitions against adulteration and misbranding, notification,

repair/replace/ refund, recall, records and reports, and adherence to Good Manufacturing Practices (GMPs). Although a number of Class I devices still require pre-market notification, approximately three-fourths are low risk devices that FDA has exempted from premarket notification. Examples of such devices include oxygen masks and manual surgical instruments such as scalpels and tissue retractors.

Class II devices, presenting greater concern, are subject to "special controls" such as postmarket surveillance studies and performance standards, in addition to the general controls. On the risk spectrum these are the next category of devices about which the technology is well understood but we need to review data about the performance of the device, usually through bench test data. The highest risk devices are those that represent new technology. These are Class III devices, which include many implanted and life-supporting or life-sustaining devices, are subject to more stringent controls and requirements, including premarket review. For these devices, comprehensive evaluation, including data from clinical studies, is required to ensure safety and effectiveness. This involves bench and animal tests, clinical trials, the submission of a Premarket Approval Application (PMA), and in many cases review by an outside advisory panel. Examples of devices in this category include heart valves, implantable defibrillators, and computerized microscopes that automatically read Pap smears.

New devices are classified automatically into Class III and require approval unless they are either shown to be substantially equivalent to another device for which pre-market approval is not required or they are reclassified. The vast majority of devices (approximately 98%) enter the market through this premarket notification process. Examples include hearing aids; hip implants; CT, ultrasound, x-ray, and MRI imaging devices; and surgical lasers.

Quality systems for device manufacture

FDA inspects manufacturing facilities to be sure they are in compliance with "good manufacturing practices" (GMPs). FDA published a quality system regulation (21 CFR Parts 808, 812 and 820) (5) which revised GMPs by adding design control requirements. The new quality systems regulation will enhance consumer protection by reducing the number of recalls from poorly designed devices and resultant patient injuries. It has been estimated that nearly half of the 1200 device product recalls conducted annually are attributed to device design. The new regulations also are consistent with quality system requirements worldwide; this meets an important goal of global harmonization.

Adverse effects reporting

Postmarket surveillance of already-marketed devices is a vital complement to the premarket review program, because no system of premarket review, no matter how thorough, can prevent all potential safety problems once a device is in widespread use. The regulation of medical devices presents unique challenges. To address these challenges requires both breadth and depth of scientific capabilities. The FDA must maintain staffing and expertise of the following scientists in order to keep pace with advances:

- Engineers (including biomedical, electrical/ electronics, and materials).
- Biologists and microbiologists
- Physicians and other clinicians
- Chemists, biochemists and toxicologists
- Pharmaceutical technologists
- Physicists
- Statisticians
- Consumer safety officers and field investigators
- Human factors specialists

Conclusion

It is necessary to commit scientifically sound regulatory environment that will provide consumers with the best medical care. This includes continued services to small manufacturers, readily available guidance on FDA requirements, predictable and reasonable response times on applications for marketing, and equitable enforcement. But in the public interest, this commitment to the industry must be coupled with a reciprocal commitment: that medical device firms will meet high standards in the design, manufacture, and evaluation of their products. The protections afforded our consumer, and the benefits provided the medical device industry, cannot be underestimated.

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