

FDA



www.fda.gov

“Design of Biomedical Devices and Systems”,
2nd Edition, King & Fries, CRC Press, 2009.

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FDA Organization

FDA is an agency within the [Department of Health and Human Services](#).

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation, and by regulating the manufacture, marketing, and distribution of tobacco products.

The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods, and to reduce tobacco use to improve health.

Organization

The FDA's organization consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods, Global Regulatory Operations and Policy, and Operations.

Office of the Commissioner

- [About the Office of the Commissioner](#)
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Office of Medical Products and Tobacco

Provides advice and counsel to the Commissioner on all medical product and tobacco-related programs and issues.

- [Office of Medical Products and Tobacco](#)
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FDA's Mission Statement

- *“The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.”*

<http://www.fda.gov/AboutFDA/CentersOffices/default.htm>

What FDA Regulates

- **“Biologics**
 - *product and manufacturing establishment licensing*
 - *safety of the nation's blood supply*
 - *research to establish product standards and develop improved testing methods*
- **Cosmetics**
 - *safety*
 - *labeling*
- **Drugs**
 - *product approvals*
 - *OTC and prescription drug labeling*
 - *drug manufacturing standards*
- **Foods**
 - *labeling*
 - *safety of all food products (except meat and poultry)*
 - *bottled water”*

<http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm>

What FDA Regulates

- **“Medical Devices**
 - *premarket approval of new devices*
 - *manufacturing and performance standards*
 - *tracking reports of device malfunctioning and serious adverse reactions*
- **Radiation-Emitting Electronic Products**
 - *radiation safety performance standards for microwave ovens, television receivers, diagnostic*
 - *x-ray equipment, cabinet x-ray systems (such as baggage x-rays at airports), laser products,*
 - *ultrasonic therapy equipment, mercury vapor lamps, and sunlamps*
 - *accrediting and inspecting mammography facilities*
- **Veterinary Products**
 - *livestock feeds*
 - *pet foods*
 - *veterinary drugs and devices”*

<http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm>

What FDA Does Not Regulate

- **“Advertising**

- The [Federal Trade Commission](#) is the federal agency which regulates all advertising, excluding prescription drugs and medical devices. FTC ensures that advertisements are truthful and not misleading for consumers. Consumers may write to FTC at 6th St. and Pennsylvania Ave., N.W., Washington, DC 20580; telephone (202) 326-2222.
- **Alcohol**
The labeling and quality of alcoholic beverages are regulated by the Treasury Department's [Bureau of Alcohol, Tobacco, and Firearms](#). ATF's address is 650 Massachusetts Ave., N.W., Washington, DC 20226; telephone (202) 927-7777.

- **Consumer Products**

- While FDA regulates a large portion of the products that consumers purchase, the agency has no jurisdiction over many household goods. The [Consumer Product Safety Commission](#) (CPSC) is responsible for ensuring the safety of consumer goods such as household appliances (excluding those that emit radiation), paint, child-resistant packages, and baby toys. Consumers may send written inquiries to CPSC, Washington, DC 20207. CPSC operates a toll-free hot line at (800) 638-2772 or TTY (800) 638-8270 for consumers to report unsafe products or to obtain information regarding products and recalls.

- **Drugs of Abuse**

- Illegal drugs with no approved medical use--such as heroin and marijuana--are under the jurisdiction of the [Drug Enforcement Administration](#). FDA assists DEA in deciding how stringent DEA controls should be on drugs that are medically accepted but that have a strong potential for abuse. DEA establishes limits on the amount of these prescription drugs that are permitted to be manufactured each year. Inquiries regarding DEA activities may be sent to the Drug Enforcement Administration, U.S. Department of Justice, Washington, DC 20537; telephone (202) 307-1000.”

What FDA Does Not Regulate

- **“Health Insurance**
 - FDA does not regulate health insurance, the cost of health care products or procedures, or reimbursement for health and medical expenses. Questions about [Medicare](#) should be directed to the [Centers for Medicare and Medicaid Services](#).
- **Meat and Poultry**
 - The U.S. Department of Agriculture's [Food Safety and Inspection Service](#) is responsible for the safety and labeling of traditional meats and poultry. (FDA regulates game meats, such as venison, ostrich and snake.) Consumers with questions regarding meat or poultry, including safe handling and storage practices, should write or call the Food Safety Inspection Service's Meat and Poultry Hotline, Room 2925S, Washington, DC 20250; telephone (800) 535-4555.
- **Pesticides**
 - FDA, [USDA](#), and the [Environmental Protection Agency](#) share the responsibility for regulating pesticides. EPA determines the safety and effectiveness of the chemicals and establishes tolerance levels for residues on feed crops, as well as for raw and processed foods. These tolerance levels (the amount of pesticide allowed to be present in a food product) are normally set 100 times below the level that might cause harm to people or the environment. FDA and USDA are responsible for monitoring the food supply to ensure that pesticide residues do not exceed the allowable levels in the products under their jurisdiction. Public inquiries regarding EPA should be mailed to U.S. Environmental Protection Agency, Office of Pesticide Programs Public Docket (7506C), 3404, 401M St., Washington, DC 20460; telephone (202) 260-2080.”

<http://www.fda.gov/AboutFDA/WhatWeDo/WhatFDADoesntRegulate/default.htm>

What FDA Does Not Regulate

- **“Restaurants and Grocery Stores**
 - *Inspections and licensing of restaurants and grocery stores are typically handled by local county health departments.*
- **Water**
 - *The regulation of water is divided between the [Environmental Protection Agency](#) and FDA. EPA has the responsibility for developing national standards for drinking water from municipal water supplies. FDA regulates the labeling and safety of bottled water.”*

<http://www.fda.gov/AboutFDA/WhatWeDo/WhatFDADoesntRegulate/default.htm>

How FDA Protects the Public Health – Major Efforts

- “[MedWatch](http://www.fda.gov/medwatch/) -- FDA provides safety information on drugs and other FDA-regulated products, and allows for adverse event reporting.” <http://www.fda.gov/medwatch/>
- “[Recalls](http://www.fda.gov/opacom/7alerts.html) -- FDA posts significant product actions of the last 60 days.” <http://www.fda.gov/opacom/7alerts.html>
- “[Inspections](http://www.fda.gov/ora/inspect_ref/default.htm) - FDA inspects processing plants and other agency-regulated facilities.” http://www.fda.gov/ora/inspect_ref/default.htm
- “[Advisory Committees](http://www.fda.gov/oc/advisory/default.htm) - FDA convenes public meetings with outside experts for advice on making key public health decisions.” <http://www.fda.gov/oc/advisory/default.htm>

<http://www.fda.gov/Safety/default.htm>

Recalls

- **LifePak CR Plus Automated External Defibrillators**

- **Audience:** Emergency medical personnel, other healthcare professionals
[Posted 09/11/2008] Physio Control, Inc., issued a recall of LifePak CR Plus Automated External Defibrillators (AED), used by emergency or medical personnel to treat adults in cardiopulmonary arrest. The product was recalled because the AED instructs the responder by voice prompts to press the shock button which is not visible because it is covered, thereby making the responder unable to provide shock therapy. The AED device should be removed from service, or the manufacturer-provided diagram should be consulted to remove and discard the shock button cover.

- **Disposable Battery Operated Lavage System (BOLS)**

- **Audience:** Operating room, outpatient and emergency room supervisory staff and physicians, risk managers
[Posted 09/08/2008] FDA notified healthcare professionals about the potential for sparks, fires, toxic fumes, and explosions when disposable battery operated lavage systems' (BOLS) cables are cut. BOLS are used in the OR, ER, burn units, and nursing units. The cutting of the battery pack's cable can lead to a short circuit, causing the batteries to discharge rapidly, producing intense heat and flammable gases with a resulting explosion that expels flammable gases and toxic chemicals endangering both patients and staff. Recommendations for avoiding this risk are provided in the medical device safety alert.

- <http://www.fda.gov/medwatch/safety/2008/safety08.htm>

Devices

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Search **go**

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Device Advice

Medical Devices

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Device Advice: Comprehensive Regulatory Assistance

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Device Advice: Comprehensive Regulatory Assistance

Search Device Advice



Information for regulated industry on determining how to comply with the federal laws and regulations governing medical devices.

Additional Information

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History of the FDA and Medical Devices

- 1906 – “the FDA enacted its first regulations addressing public health” although did not address medical devices directly.
- 1938 – Passage of the Federal Food, Drug and Cosmetic (FFD&C) Act to regulate medical devices
- Early 60’ s – the FDA concentrated on drugs and cosmetics.
- Mid 60’ s – Electrical Engineers began designed devices for medical applications
- 1969 – the Cooper Committee was formed to address issues with medical devices.
- 1976 – the FDA created amendments to the FFD&C “to assure that medical devices were safe, effective and properly labeled for intended use.

History of the FDA and Medical Devices

- 1978 – using these amendments, the FDA issued good manufacturing practices (GMPs) which “represents a quality assurance program intended to control the manufacturing, packaging, storage, distribution, and installation of medical devices”.
- 1990 – “the Safe Medical Devices Act (SMDA) was passed by Congress to give the FDA authority to add preproduction design validation controls the GMPs”.
- 1996 - the new medical device reporting (MDR) regulation was enacted “to provide a mechanism for the FDA and manufactures to indentify and monitor significant adverse events involving medical devices”.

SMDA

- “Report device-related deaths to the FDA and the device manufacturer
- Report device-related serious injuries and serious illnesses to the manufacturer or to the FDA in the manufacturer is not known
- Submit to the FDA on a semiannual basis a summary of all reports submitted during that period.
- 1996 – a new quality system (QS) regulation was put into effect incorporating the required design controls.”

“Design of Biomedical Devices and Systems”, 2nd Edition, King & Fries, CRC Press, 2009.

Classify Your Device

Device Regulation
▶ Medical Device Classification
Does the Product Emit Radiation?
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Classify Your Medical Device

- Introduction
- How To Determine Classification

Introduction

The Food and Drug Administration (FDA) has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. 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:

Device Class and Regulatory Controls

1. Class I General Controls
 - With Exemptions
 - Without Exemptions
2. Class II General Controls and Special Controls
 - With Exemptions
 - Without Exemptions
3. Class III General Controls and Premarket Approval

The class to which your device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market. If your device is classified as Class I or II, and if it is not exempt, a 510k will be required for marketing. All devices classified as exempt are subject to the limitations on exemptions. Limitations of device exemptions are covered under 21 CFR xxx.9, where xxx refers to Parts 862-892. For Class III devices, a premarket approval application (PMA) will be required unless your device is a preamendments device (on the market prior to the passage of the medical device amendments in 1976, or substantially equivalent to such a device) and PMA's have not been called for. In that case, a 510k will be the route to market.

Device classification depends on the *intended use* of the device and also upon *indications for use*. For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication is added in the device's labeling such as, "for making incisions in the cornea". Indications for use can be found in the device's labeling, but may also be conveyed orally during sale of the product. A discussion of the meaning of intended use is contained in [Premarket Notification Review Program K86-3](#).

In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

As indicated above all classes of devices are subject to General Controls. General Controls are the baseline requirements of the Food, Drug and Cosmetic (FD&C) Act that apply to all medical

Device Classes

- “**Class I** - General Controls – Non Life Sustaining - **Most exempt from Pre-Market Notification**
 - Class I devices are subject to the least regulatory control.
 - minimal potential for harm to the user and are often simpler in design than Class II or Class III devices.
 - Examples of Class I devices include *elastic bandages, examination gloves, and hand-held surgical instruments.*
- **Class II** - Special Controls – Non Life Sustaining Most require - **Pre-Market Notification (501k)**
 - Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness
 - Examples of Class II devices include *powered wheelchairs, infusion pumps, and surgical drapes.*
- **Class III** - Premarket Approval - Life Sustaining or Life Supporting - **Most require Pre-Market Approval 501k Plus Clinical Data**
 - Class III is the most stringent regulatory category for devices.
 - Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls.
 - Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.
 - Premarket approval is the required process of scientific review to ensure the safety and effectiveness of Class III devices.
 - Examples of Class III devices which currently require a premarket notification include *implantable pacemaker pulse generators and endosseous implants.* “

Device Classification Panels

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/UCM051530>

Most medical devices can be classified by finding the matching description of the device in Title 21 of the Code of Federal Regulations (CFR), Parts 862-892. FDA has classified and described over 1,700 distinct types of devices and organized them in the CFR into 16 medical specialty "panels" such as Cardiovascular devices or Ear, Nose, and Throat devices. These panels are found in Parts 862 through 892 in the CFR. For each of the devices classified by the FDA the CFR gives a general description including the intended use, the class to which the device belongs (i.e., Class I, II, or III), and information about marketing requirements. Your device should meet the definition in a classification regulation contained in 21 CFR 862-892.

Device Classification Panels

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/UCM051530>

How to Locate Classification Regulations

[868](#) Anesthesiology

[870](#) Cardiovascular

[862](#) Clinical Chemistry and Clinical Toxicology

[872](#) Dental

[874](#) Ear, Nose, and Throat

[876](#) Gastroenterology and Urology

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[886](#) Ophthalmic

[888](#) Orthopedic

[890](#) Physical Medicine

[892](#) Radiology

Where to Proceed From Classification

If your device requires premarket notification [510(k)] proceed to the Premarket Notification [510(k)] page. For Class I devices exempt from [510(k)] the submission of a [510(k)] and marketing clearance from FDA is not required. If your Class I (or certain class II) device is exempt, subject to the limitations on exemptions, from the 510(k) process, this will be stated in the classification regulation. However, other General Controls such as [registration and listing](#), [labeling](#), and [good manufacturing practices](#) apply. If you have a Class III device requiring premarket approval (PMA) proceed to

Premarket Approval (PMA) page.

Registration and Listing

Section 510 of the FFD&C

- Determine Substantial Equivalency
 - New device compared to marketed device
 - If comparable, then may get through without full testing.
- Regular 510(k) submission
 - Types
 - Identical
 - Equivalent but not identical
 - Complex devices or major differences
 - Software controlled devices
 - Format
 - Descriptor of device
 - Evidence of performance including both non-clinical and clinical testing and conclusions drawn from these tests
 - Certification
- Special 510(k)
 - E.g. Device Modification
- Special Approval for Class III Devices

“Design of Biomedical Devices and Systems”, 2nd Edition, King & Fries, CRC Press, 2009.

501(k) Determining Substantial Equivalency

Design of Biomedical Devices and Systems, 3rd Ed., King, et.al. CRC Press 2015

