



[Home](#) > [About FDA](#) > [Centers & Offices](#) > [About the Center for Devices and Radiological Health](#)

About FDA

Overview of Medical Devices and Their Regulatory Pathways

Medical Devices: The Basics

The definition has several components. A medical device:

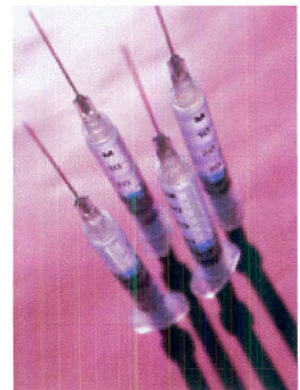
- diagnoses, cures, lessens, treats, or prevents disease
- affects the function or structure of the body
- does not achieve primary intended purposes through chemical action

FDA's Center for Devices and Radiological Health regulates companies that design, manufacture, repackage, relabel and/or import medical devices into the United States. The agency does not regulate the practice of medicine – how and which physicians can use a device. The only exception is FDA's regulation of mammography facilities under the Mammography Quality Standards Act.

What's a combination product?

Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. The term acknowledges the role technological advancements have made in merging medical product types. Examples of combination products include a drug-eluting stent, a nicotine patch, surgical mesh with antibiotic coating, prefilled syringes, and a steroid-eluting pacing lead.

Combination products raise regulatory challenges because they involve components that were normally regulated under different types of authorities and often by different FDA Centers. Differences in regulatory pathways for each component can affect the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications.



Medical Device Law

The long legal journey toward medical device regulation began with the Pure Food and Drugs act of 1906. Medical devices were not included as no one envisioned how technology would grow increasingly complex and need to be regulated. The **Medical Device Amendments of 1976** gave FDA authority to ensure the safety and effectiveness of a range of life-saving medical devices while also protecting the public from fraudulent devices. The Amendments:

- defined a medical device,
- established three device classes (I, II, and III),
- identified pathways to market,
- established Advisory Panels, and
- set clinical investigation requirements.

Subsequent legislation strengthened the FDA's regulatory authority:

Table 1: Major Medical Device Legislation

Legislation	Significance
Safe Medical Devices Act of 1990	• established Quality System requirements
	• supported postmarket surveillance
	• allowed FDA discretion for PMAs brought to panel

FDA Modernization Act of 1997

- supported for early collaboration, expanded Class I and Class II exemptions
- set the "least burdensome provision"*
- supported dispute resolution
- established evaluation of automatic Class III designation (giving the sponsor the opportunity to request lower classification due to a minimal risk device, known as "de novo" review)

Medical Device User Fee and Modernization Act (MDUFMA) of 2002

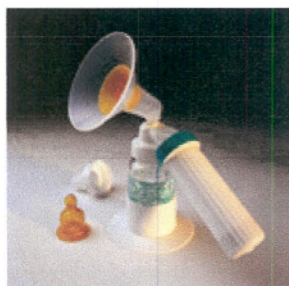
- mandated free and open participation by all interested persons
- established a fee schedule for most types of device submissions to achieve shorter review times
- requires FDA to include pediatric experts on the panel for a product intended for pediatric use

FDA Modernization Act of 2007

- reauthorized and expanded MDUFMA

*The **least burdensome provision** allows industry and FDA to consider the least burdensome appropriate means of evaluating a device's effectiveness when there's a reasonable likelihood of its approval. The intent is to help expedite the availability of new device technologies without compromising scientific integrity in the decision-making process or FDA's ability to protect the public health. This provision does **not** lower the standard for premarket clearance and approval.

Three classes of regulatory control



The three device classes are based on the degree of regulatory control necessary to ensure their safety and effectiveness:

Class I devices present a low risk of harm to the user and are subject to general control that are sufficient to protect the user. Most are exempt from the regulatory process.

Examples: non-powered breast pumps, elastic bandages, tongue depressors, examination gloves, most hearing aids, arm slings, microbial analyzers, keratoscopes

Class II devices are more complicated and require special controls for labeling, guidance, tracking, design, performance standards, and postmarket

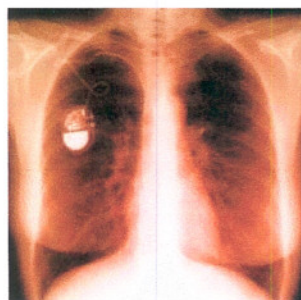
monitoring. Most require Premarket Notification 510(k).

Examples: powered wheelchairs, CT scanners, contact lens care products, endolymphatic shunts



Class III devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. They have the toughest regulatory controls. Most of these devices require Premarket Approval because general and special controls alone cannot reasonably assure their safety and effectiveness.

Examples: pacemakers, implanted weight loss devices, non-invasive glucose testing devices, medical imaging analyzers, cochlear implants, breast implants



How a Device Gets to Market

A device's journey to the market can take one of four major pathways:

1. Investigational Device Exemptions (IDE)

2. Premarket Notification (510(k))
3. Premarket Approval Application (PMA)
4. Humanitarian Device Exemption (HDE)

Investigational Device Exemptions (IDE)

An IDE allows an investigational device to be used in a clinical study to collect the safety and effectiveness data required for a Premarket Approval (PMA) application or a Premarket Notification (510(k)) submission to FDA. Clinical studies with devices of significant risk must be approved by FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with devices posing non-significant risk must be approved by the IRB only before the study can begin.

FDA observes a 30-day review period. The agency primarily reviews the device's safety data and makes recommendations regarding effectiveness. If there's no action by FDA within the 30-day period, the device is considered approved.

Premarket Notification (510(k))

510(k) is required when demonstrating substantial equivalence to a legally marketed device, when making significant modifications to a marketed device, and when a person required to register with FDA introduces a device for the first time. If a device requires the submission of a 510(k), it cannot be commercially distributed until the FDA authorizes it.

Substantial Equivalence

A device is substantially equivalent (SE) if it has the same intended use and same technological characteristics as a legally marketed device, known as the predicate. A legally marketed device:

1. was legally marketed prior to May 28, 1976 ("preamendments device"), for which a PMA is not required, or
2. was reclassified from Class III to Class II or Class I, or
3. was found SE through the 510(k) process.

Applicants must compare their device to one or more similar legally marketed devices and make and support their SE claims. If the device is SE to a predicate, it is placed in the same class. If it is not SE, it becomes non-SE and is placed into Class III.

Examples of 510(k)s include x-ray machines, dialysis machines, fetal monitors, lithotripsy machines, and muscle stimulators.

Premarket Approval (PMA)

PMA refers to the scientific and regulatory review necessary to evaluate the safety and effectiveness of Class III devices or devices that were found not substantially equivalent to a Class I or II predicate through the 510(k) process.

PMA is the most involved process. To reasonably assure that a device is safe and effective, PMA requires valid scientific evidence that the probable benefits to health from the intended use of a device outweigh the probable risks, and that the device will significantly help a large portion of the target population. Sources of valid scientific evidence may include well controlled investigations, partially controlled studies, historical controls, well documented case histories by qualified experts, and robust human experience.

Independence is an important concept for PMAs, meaning that each PMA should establish the safety and effectiveness of the device under review, and that data about one device cannot be used to support another.

Examples of PMAs include digital mammography, minimally invasive and non-invasive glucose testing devices, implanted defibrillators, and implantable middle ear devices.

Table 2: Summary Comparison of 510(k) and PMA

510(k) Submissions	PMA Submissions
<ul style="list-style-type: none"> • primarily for Class II devices 	<ul style="list-style-type: none"> • primarily for Class III devices
<ul style="list-style-type: none"> • a Class I or II preamendment or legally marketed device (predicate) exists 	<ul style="list-style-type: none"> • a Class I or II preamendment or legally marketed device (predicate) does not exist
<ul style="list-style-type: none"> • third party review option is available for devices not requiring clinical data 	<ul style="list-style-type: none"> • device is life supporting and/or has potential risk to patient
<ul style="list-style-type: none"> • documented proof of 	<ul style="list-style-type: none"> • documented safety and effectiveness data for the device

Substantial Equivalence to a predicate is required is required

Humanitarian Device Exemption (HDE)

An HDE is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. HDEs are exempt from requirements to demonstrate effectiveness. Still, they must pose no unreasonable risks, or at least the probable benefits should outweigh the risks. And the device must be used at a facility with an Institutional Review Board.

HDEs provide a powerful incentive for device manufacturers to develop devices that help diagnose or treat patients with rare conditions. Otherwise, a company's research and development costs would likely exceed the market returns for serving such small patient populations.

Examples of HDEs include a fetal bladder stent, iris replacement, radioactive microspheres for cancer treatment, an semi-constructed finger joints.

Post-Approval Studies

FDA can impose requirements at the time of approval of a PMA or HDE, or by regulation afterwards. One requirement may be the need for post-approval studies. The CDRH Post-Approval Studies Program helps ensure the well designed post-approval studies are conducted effectively and efficiently and in the least burdensome manner. Post-approval studies should not be used to evaluate unresolved premarket issues that are important to the initial establishment of device safety and effectiveness.

With post-approval studies, FDA can evaluate device performance and potential problems when the device is used more widely than in clinical trials and over a longer period of time. This allows FDA to build in accountability and gather essential postmarket information, including:

- longer-term performance of the device (for example, effects of re-treatments and product changes)
- community performance (clinicians and patients)
- effectiveness of training programs
- sub-group performance
- outcomes of concern – real and potential

Links on this page: