



Food and Drug Administration and Assistive Technology Frequently Asked Questions

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What Is the Role of the Food and Drug Administration (FDA) Relative to Assistive Technology?

The FDA regulates medical devices to assure their safety and effectiveness. The Center for Devices and Radiological Health (CDRH) is the branch of the FDA responsible for regulating medical devices and electronic radiation-emitting products.

What Is the FDA's Legal Authority for Regulating Medical Devices?

The FDA had been regulating the marketing of drugs. In 1976, Congress expanded the responsibilities of the FDA to include the regulation of medical devices by passing the Medical Device Amendments (the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq.). The amendments were prompted by a proliferation of sophisticated medical devices, including some that failed. Some states such as California had begun to require pre-market approval for medical devices. With the passage of the Medical Device Amendments, oversight passed to the federal agency. In fact, pursuant to 21 C.F.R. § 360k(a), state law that differs from or adds to the federal mandates is expressly pre-empted.

Is There Is Definition of "Medical Device?"

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h), defines "medical device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;

- (2) 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
- (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.”

When determining whether the device fits within the definition of “medical device,” the FDA may look at the *intended uses* of the device, as evidenced by such things as promotional materials, advertising, and distributional material. In *United States v. Universal Management Services, Inc.*, 191 F.3d 750 (6th Cir. 1999), the court held that a product which was essentially an electric gas grill igniter was a “medical device” pursuant to the Federal Food, Drug, and Cosmetic Act because it was marketed as a device to relieve pain.

Are All Medical Devices Equally Regulated?

No. Devices are placed in one of three classes, based on the degree of regulatory control required to assure safety and effectiveness. The classes are defined in 21 C.F.R. § 860.3.

Class I devices are subject to only general controls, which are the baseline requirement for all medical devices. According to the FDA website, “[s]ome Class I devices are exempt from the premarket notification and/or parts of the good manufacturing practices regulations. Approximately 572 or 74% of the Class I devices are exempt from the premarket notification process.” <http://www.fda.gov/cdrh/devadvice/313.html>.

A device falls into Class I if:

- general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device; or
- there is insufficient information to determine whether general controls are sufficient, but the device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury.

Class II devices are or will be subject to special controls because general controls are considered insufficient. Special controls may include promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidance documents, recommendations, and other appropriate actions, as the Commissioner deems necessary.

Class III devices are generally subject to pre-market approval. A Class III device is life-supporting or life-sustaining; or its use is of substantial importance in preventing impairment of human health; or the device presents a potential unreasonable risk of illness or injury. Once a device has received pre-market approval, the FDA mandates that it be made with almost no deviations from the specifications in its approval application. *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1007 (2008).

What Is an Example of a Class I Device?

A cane is a Class I device. Pursuant to 21 C.F.R § 890.3075(a), a cane is “a device intended for medical purposes that is used to provide minimal weight support while walking. Examples of canes include the following: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end.”

What Does That Mean in Terms of FDA Regulation?

A cane is subject to general controls. Pursuant to 21 C.F.R. § 890.3075(b), a cane is exempt from pre-market notification procedures and current good manufacturing practice requirements (with the exception of general requirements concerning records and complaint files). That means that a manufacturer does not have to submit pre-market notification as long as the device has the same intended uses as the generic device and does not operate using a different fundamental scientific technology than a legally marketed device in that generic type of device.¹ 21 C.F.R. § 890.9.

Do All Medical Devices Have Their Own Regulatory Provision?

A number of medical devices have regulatory provisions. For example, those devices described as physical medicine devices are set forth in 21 C.F.R. Part 890, while hearing aids and tinnitus maskers are listed in Part 874 as ear, nose and throat devices. Listings of devices are not intended to be exhaustive lists of every device that is, or will be, subject to regulation. See 21 C.F.R §§ 874.1(b), 890.1(b).

What Is an Example of a Class II Device?

A powered wheelchair, defined as “a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position,” is a Class II device subject to performance standards. 21 C.F.R. § 890.3860.

What Is an Example of a Class III Device?

An implantable pacemaker pulse generator is a Class III device. This device “has a power source and electronic circuits that produce a periodic electrical pulse to stimulate

¹ If the device is an in vitro device with certain designated uses, this exemption does not apply.

the heart,” and includes “triggered, inhibited, and asynchronous devices implanted in the human body.”

Do All Class III Devices Require Pre-market Approval?

No. There are two exceptions to the requirement that Class III devices obtain pre-market approval and many devices fall within these exceptions:

If a device was already on the market when the Medical Device Amendments were passed, the device may remain on the market until the FDA promulgates a regulation requiring pre-market approval for that device; or

A new device need not undergo the pre-market approval process if the FDA finds that it is “substantially equivalent” to another device exempt from pre-market approval. The agency review of the device to determine whether it is substantially equivalent is known as a 501(k) process, named after the section of the Medical Device Amendments that authorizes the process. See *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, at 1004.

How Does FDA Regulation Relate to Funding of Assistive Technology Issues?

Some funding sources exclude from coverage medical devices that are not approved by the FDA. For example, the regulations governing Veterans Benefits specifically exclude medical devices not approved by the FDA unless the treating medical facility is conducting formal clinical trials under an Investigational Device Exemption, or the device is prescribed under a compassionate use exemption. 38 C.F.R. § 17.38(c)(3).

State Medicaid agencies may attempt to exclude devices not approved by the FDA. For example, in New York State, prior approval requests for a certain type of enclosed bed were denied because they were not FDA approved. The denials were successfully challenged because the definition of “durable medical equipment” under state law did not include a requirement that an item be FDA approved. Those fair hearing decisions can be obtained from the author at the National Assistive Technology Project, 716-847-0655, extension 220.

It can be problematic when a funding source requires “FDA approval.” As can be seen from the information above, very few medical devices actually need “approval” as defined by the FDA.