How to Determine if Your Product is a Medical Device

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Introduction

Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers, and closed loop artificial pancreas systems. Additionally, medical devices include in vitro diagnostic (/medical-devices/products-and-medical-procedures/in-vitro-diagnostics) (IVD) products, such as reagents, test kits, and blood glucose meters. Certain radiation-emitting electronic products (/medical-devices/classify-your-medical-device/does-product-emit-radiation) that have a medical use or make medical claims are also considered medical devices. Examples of these include diagnostic ultrasound products, x-ray machines and medical lasers.

Device Determination Steps

The following steps may be helpful when trying to determine if a product is regulated by the FDA as a medical device.

- Step 1: Determine if your product meets the definition of a medical device per Section 201(h) of the Food, Drug & Cosmetic Act.
- Step 2: Determine if an appropriate product classification exists for your product

Step 1: Determine if your product meets the definition of a medical device

The FDA considers a product to be a device, and subject to FDA regulation, if it meets the definition of a medical device per Section 201(h) of the Food, Drug, and Cosmetic Act.

> *Per Section 201(h)(1) of the Food, Drug, and Cosmetic Act, a device is:*
> *An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:*

- *(A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
- *(B) 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*
- *(C) 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. The term "device" does not include software functions excluded pursuant to section 520(o).*

To determine if your product meets the definition of a medical device, you should define the intended use and indications for use of your product. Once you have defined the intended use and indications for use of your product, you can determine if the product meets the definition of a medical device.

Intended Use	Indications for use
The general purpose of the device or its function. This includes the indications for use.	Describes the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.

Step 2: Determine if an appropriate product classification exists for your product

In determining if your product is regulated as a medical device, it may also be helpful to search for existing product classifications that may apply to your product. Finding an existing classification that describes your product's intended use or design is a good indicator that it might be a medical device. Three methods to determine if a product classification exists for your product are outlined below. For further information on how to classify a medical device, please refer to the Classify Your Device (/medical-devices/overview-device-regulation/classify-your-medical-device) page.

Method 1: Search the Product Classification Database

You may search the FDA Product Classification Database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) to determine if there is an existing product classification that applies to your product:

- Use the Quick Search (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/pcdsimplesearch.cfm) feature to search by keyword(s). Please note, you may need to conduct multiple searches using a variety of keywords that describe your product (for example, search both "stent" and "stents").
- Use the Advanced Search (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm) feature to search by product code, regulation number, or device class.

Method 2: Search for Similar Devices

If you identify a similar device legally marketed in the United States, you may search for an FDA letter or order that permits market authorization. The information in the letter or order for a similar device type might help you determine the classification of your device.

The FDA decisions that permit marketing authorization are public information and may be found by searching the following databases, using either the Quick Search or Advanced Search feature:

- Premarket Approval (PMA) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm) – Most Class III (high risk) devices require Premarket Approval (PMA) (/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma) before they may be legally marketed. This database includes devices with Premarket Approval, and includes the approval order, Summary of Safety and Effectiveness, and labeling for the approved device (original PMAs and panel-track supplements).
- Premarket Notification 510(k) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm) – Most Class II (moderate risk) devices require 510(k) (/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k) clearance from the FDA before they may be legally marketed. This database includes releasable 510(k) information.
- De Novo (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm) – De Novo (/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request) provides a possible route to classify novel devices of low to moderate risk. This database includes De Novo classification orders and transparency summaries.

- Humanitarian Device Exemption (HDE) (/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/humanitarian-device-exemption) provides is a possible route to market medical devices that may help people with a rare diseases or conditions. This database includes devices with HDE approval, and includes the approval order, Summary of Safety and Probable Benefit, and labeling for the approved device.

Note: *Most Class I and some Class II devices may not be listed in the databases referenced above because they are exempt and do not require the FDA's review before marketing.*

Method 3: Search for Similar Devices by Device Listing

You may search for a legally marketed device's product classification by reviewing its device listing information. Device listing information can be found by searching the FDA's Establishment Registration and Device Listing database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm), using either the Quick or Advanced Search feature.

Additional Considerations

Is your product a Device Software Function?

The FDA refers to software functions that are device functions as “device software functions.” Device software functions may include “Software as a Medical Device (SaMD)” and “Software in a Medical Device (SiMD).” If a software function that meets the definition of a device is deployed on a mobile platform, it may be referred to as a “mobile medical app.” Information on mobile medical applications and how they are regulated is available on the Mobile Medical Applications (/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications) page.

The FDA considers software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device to be software as a medical device. More information is available on the Software as a Medical Device (/medical-devices/digital-health-center-excellence/software-medical-device-samd) page.

The Digital Health Policy Navigator (/medical-devices/digital-health-center-excellence/digital-health-policy-navigator) guides users through a series of questions based on published digital health policies, to provide general information to help a user assess whether a particular software function meets the device definition and, if so, whether it is the focus of FDA's oversight as a device. The tool directs users to the appropriate policies to learn more.

If you are still unsure whether your product would be considered a device software function, please contact digitalhealth@fda.hhs.gov (mailto:digitalhealth@fda.hhs.gov).

- **Is your product intended for General Wellness?**
  If your product is intended for general wellness use **only**, and is low risk, it may not be actively regulated by the FDA. For more information on how the FDA defines and regulates a general wellness product, please refer to the FDA's guidance document General Wellness: Policy for Low Risk Devices (/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices).
- **Does your product include drugs or biologics?**
  Combination products are therapeutic and diagnostic products which combine drugs, devices and biological products. If you believe your device may fit into this category, please refer to the FDA Combination Products (/combination-products) page.

What to do if your product is not a medical device

If your product does not meet the definition of a medical device, it may be regulated by another Center within the FDA. If you believe your product is regulated by another Center, you may contact that at Center to discuss the products they regulate.

- Center for Biologics Evaluation and Research (/vaccines-blood-biologics) (CBER) regulates biological products.
- Center for Drug Evaluation and Research (/drugs) (CDER) regulates human drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product may be considered a drug.
- Center for Veterinary Medicine (/about-fda/fda-organization/center-veterinary-medicine) (CVM) regulates products intended for animal use.
- Center for Tobacco (/about-fda/fda-organization/center-tobacco-products) (CTP) regulates tobacco products.

Further Assistance

If you are unable to make a device determination for your product after following the steps above, please contact the Division of Industry and Consumer Education (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) (DICE).

If after reviewing the information provided on this webpage and contacting the Division of Industry and Consumer Education (DICE), you are still unable to make a determination, you may contact the Device Determination mailbox at DeviceDetermination@fda.hhs.gov (mailto:DeviceDetermination@fda.hhs.gov).

You should include the following information within your Device Determination email request:

- *Intended Use (for example, What is the product supposed to treat or diagnose?)*
- *Physical description and mechanism of action*
- *Any claims you intend to publicly make about the product*
- *Your contact information*

If you would like a formal device determination or classification from the FDA, consider submitting a 513(g) Request. For instructions on how to submit a 513(g) Request, refer to the guidance document FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act Guidance (2012). (/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic)