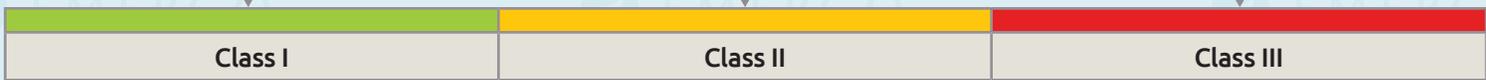


United States



The regulatory process for medical devices

Using the [FDA classification database](#), determine the classification of your device by researching "Predicate Devices" already registered in the US market. Pay special attention to the three letter Product Code and seven digit Regulation Number associated with the predicate devices you identify. If no predicate found, use [513\(g\)](#) or [De Novo process](#).



Implement Quality Management System (QMS) which meets [FDA Quality System Regulation \(QSR\)](#) found in 21 CFR Part 820. This is also commonly known as FDA Good Manufacturing Practice (GMP).

Innovative Class II, and all Class III, devices will likely require clinical studies. Get "[Pre-Submission \(Pre-Sub\)](#)" feedback from the FDA.

If clinical studies will be required, apply for an Investigational Device Exemption (IDE). Develop clinical trial protocol and conduct studies.*

Prepare and submit 510(k) premarket notification application. Pay 510(k) review fee to FDA.	Prepare* and submit Premarket Approval (PMA) application. Pay PMA submission fee to FDA.
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FDA conducts facility inspections of all major suppliers involved in the design and production of your device. All parties must be compliant with FDA QSR.

FDA issues 510(k) clearance letter; posts online.	FDA issues PMA approval letter; posts online.
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At this time, you must be in full compliance with QSRs. The FDA will not inspect Class I or II device manufacturers for compliance prior to device registration but does conduct random inspections and can issue a [Form 483](#) for non-compliance.

If you have no local presence in the US, appoint an [FDA US Agent](#) representative as a local point of contact with the FDA.

List your device and register your company using FURLS system on the FDA website in accordance with 21 CFR Part 807; contract manufacturers and sterilizers must also register and list. Specify your appointed US Agent. Your FDA Establishment Registration and Listing must be renewed on a yearly basis

You are now able to sell your device in the US. The FDA listing on their website will serve as your authorization to commercialize your device in the US. This authorization does not expire as long as certain types of changes are not made, e.g., design, intended use.

* The process of supplying clinical study data in support of a PMA submission is far more complex than presented in this chart. This is an extremely simplified and high level view of the FDA requirements regarding clinical study data.

This is a simplified overview of the process. The FDA may choose to audit your submission and request more documents, which will add time to your approval.

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5002-0914

United States



The regulatory process for medical devices

Device classification in USA	How long you should expect to wait after submission until approval is granted. (See note 1)	Validity period for device registrations. (See note 2)	Registration renewal should be started this far in advance. (See note 3)	Complexity of the registration process for this classification. (See note 4)	Overall cost of gaining regulatory approval. (See note 5)
CLASS I*	1 month	Does not expire	Not applicable	Simple Complex	Low High
CLASS II	3-6 months	Does not expire	Not applicable	Simple Complex	Low High
CLASS III**	18-30 months	Does not expire	Not applicable	Simple Complex	Low High

NOTE 1: The time frames shown above are typical for the majority of medical device submissions but assume that your device does not contain animal tissue, medicinal substances or employ entirely novel technology. Your length of approval will depend on the quality and completeness of your technical documentation and how much time you take to address additional information requests from authorities after submission. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

NOTE 2: Authorization to market your device does not expire as long as you do not make changes to the intended use, or changes to the device itself or its indications for use. However, your establishment registration (for your company) must be renewed annually, and the appropriate fees submitted. Failure to renew your annual establishment registration may result in you being prohibited from marketing your devices in the USA.

NOTE 3: The device registration does not expire, so no renewal is required. However, you must continue to pay your annual establishment registration fee for your company.

NOTE 4: Our rating of the complexity of the registration process is based on our experience and the opinion of nearly 1,000 QA/RA professionals worldwide who were asked to rate the difficulty of registering a device in each country in January 2014. The European CE Marking process is considered the mid-point to which all other markets are compared.

NOTE 5: Low = Less than US\$5000; Midpoint = US\$15000-\$30000; High = More than US\$50000. Overall cost includes registration application fees, product testing, in-country representation, submission preparation consulting and translation of registration documents but not IFU. Costs do not include cost of implementing, auditing, or updating a quality management system compliant with US FDA 21 CFR Part 820.

* Most Class I devices do not need to be cleared or approved for sale by the FDA but do need to be listed with the FDA using the FDA website. Once appropriate establishment registration fees are paid and verified, you will be able to complete the listing of your Class I device online.

** Devices which the FDA has not previously classified based on risk are automatically placed into Class III by the FDA, regardless of the level of risk they pose. Some lower risk devices without a predicate device may qualify for the "de novo" process which may result in a Class I or II designation by the FDA.

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