



What are 510(k) Clearance and Premarket Approval?

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All manufacturers who wish to market devices in the United States are required to register with the FDA and are subject to periodic audits. This article describes the marketing pathways they can choose.

Device Classification

The 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act created three categories of medical devices, based on the level of risk:

Class I: Generally, these are simple devices with minimal risk to the user. Almost all of these devices are exempt from FDA clearance or approval. Examples: enemas, crutches, elastic bandages, bedpans.

Class II: These devices pose a moderate level of risk to the user. Almost all of these devices require a regulatory submission before they can be legally marketed. As a rule, class II devices require 510(k) submissions. Examples: condoms, intravenous administration sets, sutures, inflatable blood pressure cuffs.

Class III: These devices pose a serious level of risk to the user, mostly because they are implants or sustain life. All of these devices require a regulatory submission before they can be legally marketed. As a rule, class III devices require a PMA (Premarket Approval) submission (described in further detail below). Examples: implantable pacemakers, blood vessel stents, breast implants.

Registration is required regardless of the classification. The method chosen depends on what the manufacturer wishes to claim and whether similar devices have been cleared or approved.

510(k) Clearance

The purpose of a 510(k) submission is to demonstrate that a device is “substantially equivalent” to a predicate device (one that has been cleared by the FDA or marketed before 1976). The 510(k) submitter compares and contrasts the subject and predicate devices, explaining why any differences between them should be acceptable. Human data are usually not required for a 510(k) submission; this decision is made at the discretion of the FDA. Laboratory testing is almost always a requirement. Depending on the type of 510(k), the law gives the FDA either 30 or 90 days to clear the device, ask

questions, or reject the application.

Manufacturers may also submit a 510(k) if they alter their device. Not all changes require a 510(k) submission. In general, changes to a device's intended use, contraindications, or basic operation require a new 510(k) clearance. Changes to blood-contacting materials, sterilization method, or performance specifications may also require a new 510(k).

The FDA does not “approve” 510(k) submissions. It “clears” them. It is not legal to advertise a 510(k) cleared device as “FDA-approved.”

Premarket Approval (PMA)

A PMA submission is used to demonstrate to the FDA that a new or modified device is safe and effective. This standard is higher than is required for 510(k) submissions. Human use data from a formal clinical study is almost always required in addition to laboratory studies. The FDA is required to approve, question, or reject the application within 180 days. Changes to a PMA-approved device may require a PMA supplement or even a new PMA. Manufacturers have far less leeway in modifying PMA devices than they do for changes to 510(k) devices. PMA devices can be legally advertised as “PMA-approved” or “FDA-approved.”

Checking Documents

Submissions for 510(k) and PMA are public documents except for portions that contain trade secrets, confidential commercial/financial information, or information that is personal and private (such as patient records from clinical trials). For both types of submissions, the FDA maintains searchable online databases that contain only a small amount of information. Additional documents that are releasable can be accessed through a Freedom of Information (FOI) request. The first time an FOI request is made for a submission, the FDA notifies the original submitter, who is then allowed to delete proprietary and personal information.

If searching an online database, note the current manufacturer or distributor may not be listed as the submitter in the database. This happens because the FDA database is not updated when ownership of a 510(k) or PMA is sold or transferred between business entities. So submitter information refers only to the company that made the submission. Therefore, if company A gets PMA 123 approved for their product, but later sells that product to company B, the PMA database for number 123 will list company A as the submitter, even though company A might not have made the product for many years. Also, foreign companies can have domestic firms make submissions, and consultants who write submissions might be listed as submitters.

Defrauding the FDA

Manufactures of quack devices sometimes seek clearance without telling the FDA that their device will be used differently from the predicate device. For example, several devices said to measure skin resistance are accompanied by software that fabricate diagnoses and recommends products. This set-up is illegal because the basic device has not been cleared for such purposes. In addition, the FDA would consider the software to be a separate device—very likely in Class III—that would require

premarket approval.

For Further Information

- [FDA's Device Advice](#)
- [FDA Index Page to 510\(k\) Information](#)
- [Search the FDA's Device Classification Database](#)
- [Search the 510\(k\) Database](#)
- [Search the PMA Database](#)
- [How to Get Information from the FDA](#)

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