

PREMARKET NOTIFICATION 510(k)

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Introduction

Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). There is no 510(k) form, however, [21 CFR 807 Subpart E](#) describes requirements for a 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA. Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. A legally marketed device, as described in 21 CFR 807.92(a)(3), is a device that was legally marketed prior to May 28, 1976 (preamendments device), for which a PMA is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found SE through the 510(k) process. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate." Although devices recently cleared under 510(k) are often selected as the predicate to which equivalence is claimed, any legally marketed device may be used as a predicate. Legally marketed also means that the predicate cannot be one that is in violation of the Act.

Until the submitter receives an order declaring a device SE, the submitter may not proceed to market the device. Once the device is determined to be SE, it can then be marketed in the U.S. The SE determination is usually made within 90 days and is made based on the information submitted by the submitter.

Please note that FDA does not perform 510(k) pre-clearance facility inspections. The submitter may market the device immediately after 510(k) clearance is granted. The manufacturer should be prepared for an FDA quality system (21 CFR 820) inspection at any time after 510(k) clearance.

What is Substantial Equivalence

A 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is at least as safe and effective as the predicate.

A device is substantially equivalent if, in comparison to a predicate it:

- has the same intended use as the predicate; **and**
- has the same technological characteristics as the predicate;
- or**
- has the same intended use as the predicate; **and**
- has different technological characteristics and the information submitted to FDA;
 - does not raise new questions of safety and effectiveness; **and**
 - demonstrates that the device is at least as safe and effective as the legally marketed device.

A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

A device may not be marketed in the U.S. until the submitter receives a letter declaring the device substantially equivalent. If FDA determines that a device is **not** substantially equivalent, the applicant may:

- resubmit another 510(k) with new data,
- request a Class I or II designation through the [de novo](#) process
- file a [reclassification petition](#), or
- submit a premarket approval application (PMA).

Who is Required to Submit a 510(k)

The Act and the 510(k) regulation (21 CFR 807) do not specify who must apply for a 510(k). Instead, they specify which actions, such as introducing a device to the U.S. market, require a 510(k) submission.

The following four categories of parties must submit a 510(k) to the FDA:

1. Domestic manufacturers introducing a device to the U.S. market;

Finished device manufacturers must submit a 510(k) if they manufacture a device according to their own specifications and market it in the U.S. Accessories to finished devices that are sold to the end user are also considered finished devices. However, manufacturers of device components are not required to submit a 510(k) unless such components are promoted for sale to an end user as replacement parts. Contract manufacturers, those firms that manufacture devices under contract according to someone else's specifications, are not required to submit a 510(k).

2. Specification developers introducing a device to the U.S. market;

A specification developer develops the specifications for a finished device, but has the device manufactured under contract by another firm or entity. The specification developer submits the 510(k), not the contract manufacturer.

3. Repackers or relabelers who make labeling changes or whose operations significantly affect the device.

Repackagers or relabelers may be required to submit a 510(k) if they significantly change the labeling or otherwise affect any condition of the device. Significant labeling changes may include modification of manuals, such as adding a new intended use, deleting or adding warnings, contraindications, etc. Operations, such as sterilization, could alter the

condition of the device. However, most repackagers or relabelers are not required to submit a 510(k).

4. Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/exporters introducing a device to the U.S. market.

Please note that all manufacturers (including specification developers) of Class II and III devices and select Class I devices are required to follow design controls (21 CFR 820.30) during the development of their device. The holder of a 510(k) must have design control documentation available for FDA review during a site inspection. In addition, any changes to the device specifications or manufacturing processes must be made in accordance with the Quality System regulation (21 CFR 820) and may be subject to a new 510(k). Please see our guidance, "[Deciding When to Submit a 510\(k\) for a Change to an Existing Device.](#)"

When a 510(k) is Required

A 510(k) is required when:

1. Introducing a device into commercial distribution (marketing) for the first time. After May 28, 1976 (effective date of the Medical Device Amendments to the Act), anyone who wants to sell a device in the U.S. is required to make a 510(k) submission at least 90 days prior to offering the device for sale, even though it may have been under development or clinical investigation before that date. If your device was not marketed by your firm before May 28, 1976, a 510(k) is required.
2. You propose a different intended use for a device which you already have in commercial distribution. The 510(k) regulation ([21 CFR 807](#)) specifically requires a 510(k) submission for a major change or modification in intended use. Intended use is indicated by claims made for a device in labeling or advertising. Most, if not all changes in intended use will require a 510(k). Please note that prescription use to over the counter use is a major change in intended use and requires the submission of a new 510(k).
3. There is a change or modification of a legally marketed device and that change could significantly affect its safety or effectiveness. The burden is on the 510(k) holder to decide whether or not a modification could significantly affect safety or effectiveness of the device. Any modifications must be made in accordance with the Quality System regulation, 21 CFR 820, and recorded in the device master record and change control records. It is recommended that the justification for submitting or not submitting a new 510(k) be recorded in the change control records.

A new 510(k) submission is required for changes or modifications to an existing device, where the modifications could significantly affect the safety or effectiveness of the device or the device is to be marketed for a new or different indication for use. See [Is a new 510\(k\) required for a modification to the device?](#) for additional information.

When a 510(k) is Not Required

The following are examples of when a 510(k) is not required.

1. You sell unfinished devices to another firm for further processing or sell components to be used in the assembling of devices by other firms. However, if your components are to be sold directly to end users as replacement parts, a 510(k) is required.

2. Your device is not being marketed or commercially distributed. You do not need a 510(k) to develop, evaluate, or test a device. This includes clinical evaluation. Please note that if you perform clinical trials with your device, you are subject to the [Investigational Device Exemption](#) (IDE) regulation (21 CFR 812).
3. You distribute another firm's domestically manufactured device. You may place a label on the device, "Distributed by ABC Firm" or "Manufactured for ABC Firm," ([21 CFR 801.1](#)) and sell it to end users without submission of a 510(k).
4. In most cases, if you are a repackager or a relabeler you are not required to submit a 510(k) if the existing labeling or condition of the device is not significantly changed. The labeling should be consistent with the labeling submitted in the 510(k) with the same indications for use and warnings and contraindications.
5. Your device was legally in commercial distribution before May 28, 1976 and you have documentation to prove this. These devices are "grandfathered" and have [Preamendment Status](#). You do not have to submit a 510(k) unless the device has been significantly modified or there has been a change in its intended use.
6. The device is made outside the U.S. and you are an importer of the foreign made medical device. A 510(k) is not required if a 510(k) has been submitted by the foreign manufacturer and received marketing clearance. Once the foreign manufacturer has received 510(k) clearance for the device, the foreign manufacturer may export his device to any U.S. importer.
7. Your device is exempted from 510(k) by regulation (21 CFR 862-892). That is, certain Class I or II devices can be marketed for the first time without having to submit a 510(k). A list of the Class I and II exempted devices can be found on [Medical Device Exemptions 510\(k\) and GMP Requirements](#). However, if the device exceeds the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9), such as the device has a new intended use or operates using a different fundamental scientific technology than a legally marketed device in that generic type of device, or the device is a reprocessed single-use device, then a 510(k) must be submitted to market the new device.

Preamendment Devices

The term "preamendments device" refers to devices legally marketed in the U.S. by a firm before May 28, 1976 **and** which have not been:

- significantly changed or modified since then; **and**
- for which a regulation requiring a PMA application has not been published by FDA.

Devices meeting the above criteria are referred to as "grandfathered" devices and do not require a 510(k). The device must have the same intended use as that marketed before May 28, 1976. If the device is labeled for a new intended use, then the device is considered a new device and a 510(k) must be submitted to FDA for marketing clearance.

Please note that you must be the **owner** of the device on the market before May 28, 1976, for the device to be grandfathered. If your device is similar to a grandfathered device and marketed **after** May 28, 1976, then your device does NOT meet the requirements of being grandfathered and you must submit a 510(k). In order for a firm to claim that it has a preamendments device, it must demonstrate that its device was labeled, promoted, and distributed in interstate commerce for a

specific intended use and that intended use has not changed. See [Preamendment Status](#) for information on documentation requirements.

Third Party Review Program

The Center for Devices and Radiological Health (CDRH) has implemented a Third Party Review Program. This program provides an option to manufacturers of certain devices of submitting their 510(k) to private parties (Recognized Third Parties) identified by FDA for review instead of submitting directly to CDRH. For more information on the program, eligible devices and a list of Recognized Third Parties go to [Third Party Review Program Information](#) page.

References

New Section 513(f)(2) - Evaluation of Automatic Class III Designation

<http://www.fda.gov/cdrh/modact/classiii.html>

<http://www.fda.gov/cdrh/modact/classiii.pdf>

510(k) Substantial Equivalence Decision-Making Process Flowchart

<http://www.fda.gov/cdrh/ode/dd510kse.pdf>

Premarket Notification Review Program 6/30/86 (K86-3) (blue book memorandum)

<http://www.fda.gov/cdrh/k863.html>

Deciding When to Submit a 510(k) for a Change to an Existing Device Deciding

<http://www.fda.gov/cdrh/ode/510kmod.html>

<http://www.fda.gov/cdrh/ode/510kmod.pdf>

Preamendment Status

<http://www.fda.gov/cdrh/comp/preamend.html>

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