

510(k) Clearances

Overview

Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k). This allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories. Thus, "new" devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified. Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.

Listings of CDRH Substantially Equivalent 510(k)s are normally available about the 5th of each month for the prior month. See the links on the left side of this page to find monthly listings of 510(k)s cleared by FDA.

General Information

- Deciding When to Submit a 510(k) for a Software Change to an Existing Device - Guidance for Industry and Food and Drug Administration Staff (PDF - 585KB) (/media/99785/download)
- Deciding When to Submit a 510(k) for a Change to an Existing Device - Guidance for Industry and Food and Drug Administration Staff (PDF - 1MB) (/media/99812/download)
- Required Submission of Safety and Effectiveness Information for Certain Class III Devices (/medical-devices/510k-clearances/required-submission-safety-and-effectiveness-information-certain-class-iii-devices)
- Refuse to Accept Policy for 510(k)s - Guidance for Industry and Food and Drug Administration Staff (PDF - 1.9MB) (/media/83888/download)
- The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance (/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/new-510k-paradigm-alternate-approaches-demonstrating-substantial-equivalence-premarket-notifications)
- Premarket Notification 510(k) (/premarket-notification-510k)
- Reclassification (/about-fda/cdrh-transparency/reclassification)

Federal Register Notices

- Medical Devices; Exemptions From Premarket Notification and Reserved Devices; Class I (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?IPaddress=&dbname=1998_register&docid=98-2498-filed)
- Class II (special controls) devices; exemptions from premarket notification; list (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?IPaddress=&dbname=1998_register&docid=98-1485-filed)

Older Clearances

- 510(k) Devices Cleared in 2016 (Archived) (<http://wayback.archive-it.org/7993/20171114011521/https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandC> [⌕](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)
- 510(k) Devices Cleared in 2015 (Archived) (<http://wayback.archive-it.org/7993/20170111000336/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandC> [⌕](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)
- 510(k) Devices Cleared in 2014 (Archived) (<http://wayback.archive-it.org/7993/20170111091517/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandC> [⌕](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

<https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-cleara...> 1/21/2020

- 510(k) Devices Cleared in 2013 (Archived) (<http://wayback.archive-it.org/7993/20170111091520/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances>)
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