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Medical Devices

Premarket Approval (PMA)

Please note: As of October 1, 2002, [FDA charges a fee for review of Premarket Approvals](#)¹

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Overview

Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act in order to obtain marketing clearance. Please note that some Class III preamendment devices may require a Class III 510(k). See "[Historical Background](#)"² for additional information.

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device. The PMA owner, however, can authorize use of its data by another.

The PMA applicant is usually the person who owns the rights, or otherwise has authorized access, to the data and other information to be submitted in support of FDA approval. This person may be an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. The applicant is often the inventor/developer and ultimately the manufacturer.

FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer. Before approving or denying a PMA, the appropriate FDA advisory committee may review the PMA at a public meeting and provide FDA with the committee's recommendation on whether FDA should approve the submission. After FDA notifies the applicant that the PMA has been approved or denied, a notice is published on the Internet (1) announcing the data on which the decision is based, and (2) providing interested persons an opportunity to petition FDA within 30 days for reconsideration of the decision.

The regulation governing premarket approval is located in Title 21 Code of Federal Regulations (CFR) [Part 814](#)³, Premarket Approval. A class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act and cannot be marketed.

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When a PMA is Required

PMA requirements apply to Class III devices, the most stringent regulatory category for medical devices. Device product classifications can be found by searching the [Product Classification Database](#)⁴. The database search provides the name of the device, classification, and a link to the Code of Federal Regulations (CFR), if any. The CFR provides the device type name, identification of the device, and classification information.

A regulation number for Class III devices marketed prior to the 1976 Medical Device Amendments is provided in the CFR. The CFR for these Class III devices that require a PMA states that the device is Class III and will provide an effective date of the requirement for PMA. If the regulation in the CFR states that "No effective date has been established of the requirement for premarket approval," a Class III 510(k) should be submitted.

Please note that PMA devices often involve new concepts and many are not of a type marketed prior to the Medical Device Amendments. Therefore, they do not have a classification regulation in the CFR. In this case, the product classification database will only cite the device type name and product code.

If it is unclear whether the unclassified device requires a PMA, use the three letter product code to search the PMA database and the Premarket Notification 510(k) database. These databases can be found by clicking on the hypertext links at the top of the product classification database web page. Enter only the three letter product code in the product code box. If there are 510(k)'s cleared by FDA and the new device is substantially equivalent to any of these cleared devices, then the applicant should submit a 510(k).

Furthermore, a new type of device may not be found in the product classification database. If the device is a high risk device (supports or sustains human life, is of substantial importance in preventing impairment of human health, or presents a potential, unreasonable risk of illness or injury) and has been found to be not substantially equivalent (NSE) to a Class I, II, or III [Class III requiring 510(k)] device, then the device must have an approved PMA before marketing in the U.S. Some devices that are found to be not substantially equivalent to a cleared Class I, II, or III (not requiring PMA) device, may be eligible for the de novo process as a Class I or Class II device. For additional information on the de novo process, see "[New section 513\(f\)\(2\) - Evaluation of Automatic Class III Designation: Guidance for Industry and CDRH Staff](#)"⁵.

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Devices Used in Blood Establishments

The Center for Biologic, Evaluation, Research (CBER) has expertise in blood, blood products, and cellular therapies as well as the integral association of certain medical devices with these biological products. To utilize this expertise marketing and investigational device submissions (Premarket Notification, Premarket Approval, and Investigational Device Exemption) for medical devices associated with the blood collection and processing procedures as well as those associated with cellular therapies are reviewed by CBER. Although these products are reviewed by CBER, the medical device laws and regulations still apply. The [list of medical devices reviewed by CBER](#)⁶ are available on the Internet.

In addition to CDRH guidance on Premarket Approval, [specific medical device guidance for devices reviewed by CBER](#)⁷ is available at online or by contacting:

Center for Biologics Evaluation and Research
Office of Communication, Training and Manufacturers Assistance (HFM-43)
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448 U.S.A.
Telephone Number: 301-827-2000 or 800-835-4709
Fax Number: 301-827-3843

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Data Requirements

A Premarket Approval (PMA) application is a scientific, regulatory documentation to FDA to demonstrate the safety and effectiveness of the class III device. There are administrative elements of a PMA application, but good science and scientific writing is a key to the approval of PMA application. If a PMA application lacks elements listed in the administrative checklist, FDA will refuse to file a PMA application and will not proceed with the in-depth review of scientific and clinical data. If a PMA application lacks valid clinical information and scientific analysis on sound scientific reasoning, it will delay FDA's review and approval. PMA applications that are incomplete, inaccurate, inconsistent, omit critical information, and poorly organized have resulted in delays in approval or denial of PMA applications. Manufacturers should perform a quality control audit of a PMA application before sending it to FDA to assure that it is scientifically sound and presented in a well organized format.

Technical Sections: The technical sections containing data and information should allow FDA to determine whether to approve or disapprove the application. These sections are usually divided into non-clinical laboratory studies and clinical investigations.

Non-clinical Laboratory Studies' Section: Non-clinical laboratory studies' section includes information on microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests. Non-clinical studies for safety evaluation must be conducted in compliance with [21CFR Part 58](#)⁸ (Good Laboratory Practice for Nonclinical Laboratory Studies).

Clinical Investigations' Section: Clinical investigations' section includes study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all individual subjects, results of statistical analyses, and any other information from the clinical investigations. Any investigation conducted under an Investigational Device Exemption (IDE) must be identified as such.

Like other scientific reports, FDA has observed problems with study designs, study conduct, data analyses, presentations, and conclusions. Investigators should always consult all applicable FDA guidance documents, industry standards, and recommended practices. Numerous device-specific FDA [guidance documents that describe data requirements are available](#)⁹. Study protocols should include all applicable elements described in the device-specific guidance documents.

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References

List of references for Premarket Approvals

- [SEC. 515. \[21 USC §360e\] Premarket Approval: General Requirement](#)¹⁰
- [21 CFR 814](#)¹¹
- [The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry](#)¹² 1332
- [PMA Guidance Documents](#)¹³
- [CPG Sec. 300.750 Class III Devices Subject to 515\(b\) Requirements](#)¹⁴

Other Resources

- [PMA Approvals](#) ¹⁵
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2. [/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/UCM046769](#)
3. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=814&showFR=1>
4. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>
5. [/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080195.htm](#)
6. [/BiologicsBloodVaccines/DevelopmentApprovalProcess/510kProcess/ucm133429.htm](#)
7. [/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm](#)
8. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58&showFR=1>
9. [/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm](#)
10. [/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapterVDrugsandDevices/ucm110198.htm](#)
11. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=814&showFR=1>
12. [/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085994.htm](#)
13. [/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm143067.htm](#)
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15. [/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm](#)