

§ 807.90

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a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that 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, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) A 510(k) summary as described in §807.92 or a 510(k) statement as described in §807.93.

(i) A financial certification or disclosure statement or both, as required by part 54 of this chapter.

(j) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in §807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(k) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification

are truthful and accurate and that no material fact has been omitted.

(l) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0281)

[42 FR 42526, Aug 23, 1977, as amended at 57 FR 18066, Apr. 28, 1992; 59 FR 64295, Dec. 14, 1994; 63 FR 5253, Feb. 2, 1998]

§ 807.90 Format of a premarket notification submission.

Each premarket notification submission pursuant to this part shall be submitted in accordance with this section. Each submission shall:

(a)(1) For devices regulated by the Center for Devices and Radiological Health, be addressed to the Food and Drug Administration, Center for Devices and Radiological Health (HFZ-401), 9200 Corporate Blvd., Rockville, MD 20850.

(2) For devices regulated by the Center for Biologics Evaluation and Research, be addressed to the Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448; or for devices regulated by the Center for Drug Evaluation and Research, be addressed to the Central

Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266. Information about devices regulated by the Center for Biologics Evaluation and Research is available at <http://www.fda.gov/cber/dap/devlst.htm> on the Internet.

(3) All inquiries regarding a premarket notification submission should be in writing and sent to one of the addresses above.

(b) Be bound into a volume or volumes, where necessary.

(c) Be submitted in duplicate on standard size paper, including the original and two copies of the cover letter.

(d) Be submitted separately for each product the manufacturer intends to market.

(e) Designated "510(k) Notification" in the cover letter.

[42 FR 42526, Aug. 23, 1977, as amended at 53 FR 11252, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990; 65 FR 17137, Mar. 31, 2000; 70 FR 14986, Mar. 24, 2005]

§ 807.92 Content and format of a 510(k) summary.

(a) A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. FDA will accept summaries as well as amendments thereto until such time as FDA issues a determination of substantial equivalence. All 510(k) summaries shall contain the following information:

(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device

which has been found to be substantially equivalent through the 510(k) premarket notification process;

(4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;

(5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled; and

(6) If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.

(b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:

(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification