

Federal Register: Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Non-Powered Suction Apparatus Device Intended for ...

U.S. Food & Drug Administration

[Federal Register: November 17, 2010 (Volume 75, Number 221)] [Notices] [Page 70271-70272] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr17no10-101]

----- DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA-2010-D-0515] Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Non-Powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy; Availability AGENCY: Food and Drug Administration, HHS. ACTION: Notice.

----- SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)." This guidance document describes a means by which non-powered suction apparatus devices intended for NPWT may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the Federal Register, FDA is publishing a final rule to classify non-powered suction apparatus devices intended for NPWT into class II (special controls). This guidance document is immediately in effect as the special control for non-powered suction apparatus devices intended for NPWT, but it remains subject to comment in accordance with the Agency's good guidance practices (GGPs). DATES: Submit either electronic or written comments on the guidance at any time. General comments on Agency guidance documents are welcome at any time. ADDRESSES: Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4617, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit electronic comments on the guidance to <http://www.regulations.gov> [1]. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. FOR FURTHER INFORMATION CONTACT: Jiyoun M. Dang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3615, Silver Spring, MD

20993, 301-796- 5650. SUPPLEMENTARY INFORMATION: I. Background Elsewhere in this issue of the Federal Register, FDA is publishing a final rule classifying non-powered suction apparatus devices intended for negative pressure wound therapy into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for non-powered suction apparatus devices intended for negative pressure wound therapy device. Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the FD&C Act, request that FDA classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing such classification. Because of the timeframes established by section 513(f)(2) of the FD&C Act, FDA has determined, under Sec. 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance This guidance is being issued consistent with FDA's good guidance practices regulation (Sec. 10.115). The guidance represents the Agency's current thinking on non-powered suction apparatus devices intended for negative pressure wound therapy. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm> [2]. Guidance documents are also available at <http://www.regulations.gov> [1]. To receive "Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)," you may either send an e-mail request to dsmica@fda.hhs.gov [3] to receive an electronic copy of the document or send a fax request to 301-847- 8149 to receive a hard copy. Please use the document number 1701 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995 This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501- 3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 50 have been approved under OMB control number 0910-0586; the collections of information in 21 CFR 56 have been approved under OMB control number 0910-0130; and the collections of

information in 21 CFR part 801 have been approved under OMB control number 0910-0485. V. Comments Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Dated: November 10, 2010. Nancy K. Stade, Deputy Director for Policy, Center for Devices and Radiological Health. [FR Doc. 2010-28872 Filed 11-16-10; 8:45 am] BILLING CODE 4160-01-P

[SOURCE](#) [4]

Source URL (retrieved on 01/26/2015 - 4:36pm):

http://www.mdtmag.com/news/2010/11/federal-register-guidance-industry-and-food-and-drug-administration-staff-class-ii-special-controls-guidance-document-non-powered-suction-apparatus-device-intended?qt-most_popular=0

Links:

[1] <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.regulations.gov>

[2] <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

[3] <mailto://edocket.access.gpo.gov/2010/dsmica@fda.hhs.gov>

[4] <http://edocket.access.gpo.gov/2010/2010-28872.htm>