

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2010-N-0513]

Medical Devices; General and Plastic Surgery Devices; Classification of Non-Powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the non-powered suction apparatus device intended for negative pressure wound therapy (NPWT) into class II (special controls). The special control that will apply to the device is the guidance document entitled “Class II Special Controls Guidance Document: Non-Powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy.” The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability for the guidance document entitled “Class II Special Controls Guidance Document: Non-Powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy.”

DATES: *Effective Date:* December 17, 2010.

FOR FURTHER INFORMATION CONTACT: Jiyoung 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. What is the background of this rulemaking?

The Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101-629), and the Food and Drug Administration Modernization Act (the FDAMA)

(Public Law 107-250) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

FDA refers to devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the 1976 amendments), as postamendments devices. Postamendments devices are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or class II in accordance with section 513(f)(2); or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the FD&C Act), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

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 for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into 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 will, within 60 days of receiving this 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 this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on October 28, 2008, classifying the SNaP Wound Care Device into class III,

because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On November 3, 2008, Spiracur, Inc., submitted a petition requesting classification of the SNaP Wound Care Device under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name SNaP Wound Care Device, and it is identified as non-powered suction apparatus device intended for negative pressure wound therapy.

FDA has identified the following risks to health associated specifically with this type of device and the recommended measures to mitigate these risks.

- Adverse tissue reaction
- Material degradation
- Improper function of suction apparatus (e.g., reflux of waste exudate to wound, incorrect delivery of negative pressure)
- Non-compatibility with other therapeutics and diagnostics (e.g., MRI, hyperbaric chamber, defibrillation)
- Uncontrolled bleeding
- Transmission of infectious agents
- Unsafe use of device (e.g., improper wound selection, improper wound management, improper placement of dressing)

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES

Identified risk	Recommended mitigation measures
Adverse tissue reaction	Section 6. Biocompatibility. Section 7. Sterility.
Material degradation	Section 8. Stability and Shelf Life.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES—Continued

Identified risk	Recommended mitigation measures
Improper function of suction apparatus (<i>e.g.</i> , reflux of waste exudate to wound, incorrect delivery of negative pressure).	Section 9. Performance Testing.
Non-compatibility with other therapeutics and diagnostics (<i>e.g.</i> , MRI, hyperbaric chamber, defibrillation).	Section 9. Performance Testing. Section 11. Labeling.
Uncontrolled bleeding	Section 11. Labeling.
Transmission of infectious agents	Section 11. Labeling.
Unsafe use of device (<i>e.g.</i> , improper wound selection, improper wound management, improper placement of dressing).	Section 11. Labeling.

FDA believes that the special controls guidance document, in addition to general controls, address the risks to health identified in table 1 of this document and provides reasonable assurance of the safety and effectiveness of the device. Therefore, on August 7, 2009, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this device by adding 21 CFR 878.4683.

Following the effective date of the final classification rule, any firm submitting a 510(k) premarket notification for a non-powered suction apparatus device intended for negative pressure wound therapy will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirement under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the non-powered suction apparatus device intended for negative pressure wound therapy they intend to market.

II. What is the environmental impact of this rule?

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment

nor an environmental impact statement is required.

III. What is the economic impact of this rule?

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action as defined by the Executive order and so it is not subject to review under Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of this device from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect

this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Does this final rule have federalism implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to “construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain State requirements “different from or in addition to” certain Federal requirements applicable to devices. 21 U.S.C. 360k; See *Medtronic v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic*, 552 U.S. 312 (2008). The special controls established by this final rule create “requirements” to address each identified risk to health presented by these specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. Cf. *Papike v. Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997).

V. How does this rule comply with the Paperwork Reduction Act of 1995?

This final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing the guidance for the final rule. This guidance, “Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy,” references previously approved collections of information found in FDA regulations.

VI. What references are on display?

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Spiracur, Inc., November 3, 2008.

List of Subjects in 21 CFR Part 878

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

- 1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Section 878.4683 is added to subpart E to read as follows:

§ 878.4683 Non-Powered suction apparatus device intended for negative pressure wound therapy.

(a) *Identification.* A non-powered suction apparatus device intended for negative pressure wound therapy is a device that is indicated for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. It is further indicated for management of wounds, burns, flaps, and grafts.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)." See § 878.1(e) for the availability of this guidance document.

Dated: November 10, 2010.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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BILLING CODE 4160-01-P

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD 9506]

RIN 1545-BJ91

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210-AB42

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of Consumer Information and Insurance Oversight****45 CFR Part 147**

RIN 0950-AA17

[OCIO-9991-IFC2]

Amendment to the Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Amendment to interim final rules with request for comments.

SUMMARY: This document contains an amendment to interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding status as a grandfathered health plan; the amendment permits certain changes in policies, certificates, or contracts of insurance without loss of grandfathered status.

DATES: *Effective Date.* This amendment to the interim final regulations is effective on November 15, 2010.

Comment Date. Comments are due on or before December 17, 2010.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB42, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* E-OHPSCA1251amend.EBSA@dol.gov.

- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, Attention: RIN 1210-AB42.

Comments received by the Department of Labor will be posted without change to <http://www.regulations.gov> and <http://www.dol.gov/ebsa>, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIO-9991-IFC2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

- *By regular mail.* You may mail written comments to the following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIO-9991-IFC2, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *By express or overnight mail.* You may send written comments to the following address only: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIO-