Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)

Document issued on: November 10, 2010

For questions regarding this document, contact Jiyoung M. Dang, Ph.D. at (301) 796-5650 or by email at jiyoung.dang@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Plastic and Reconstructive Surgery Devices Branch
Division of Surgical, Orthopedic and Restorative Devices
Office of Device Evaluation

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. Please identify your comments with the docket number listed in the notice of availability that publishes in the *Federal Register* announcing the availability of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm233275.htm You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1702 to identify the guidance you are requesting.

Table of Contents

Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)

1. Introduction

This guidance document was developed as a special control guidance to support the classification of the non-powered suction apparatus device intended for negative pressure wound therapy (NPWT) into class II (special controls). The device 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, ulcers, flaps, and grafts. This guidance is issued in conjunction with a Federal Register notice announcing the classification of the non-powered suction apparatus device intended for NPWT.

Following the effective date of the final rule classifying the device, any firm submitting a premarket notification (510(k)) for a non-powered suction apparatus device intended for NPWT will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the provisions of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the non-powered suction apparatus device intended for NPWT. Thus, a manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with non-powered suction apparatus device intended for NPWT identified in this guidance and, (3) obtain a substantial equivalence determination from FDA prior to marketing the device.

This special control guidance document identifies the classification regulation and product code for the non-powered suction apparatus device intended for NPWT (Please refer to **Section 3. Scope)**. In addition, other sections of this special control guidance document list the risks to

health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with the non-powered suction apparatus device intended for NPWT and lead to a timely 510(k) review. This document supplements other FDA documents regarding the content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87, **Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s**.[1]

3. Scope

The scope of this document is limited to the non-powered suction apparatus device intended for NPWT, which is classified under 21 CFR 878.4683, product code OKO. This document excludes the powered suction pump device which is classified under 21 CFR 878.4780, product code OMP.

> § 878.4683 - Non-powered suction apparatus device intended for negative pressure wound therapy (NPWT).
>
> 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 the management of wounds, burns, ulcers, flaps, and grafts.

This generic type of device generally consists of the following components:

- an apparatus that generates a vacuum and is capable of creating a negative pressure environment within a sealed wound;
- dressing materials used to pack the wound as well as to seal the wound;
- conduit for fluid removal from the wound bed; and
- container to collect waste materials that are removed from the wound bed.

This generic type of device is contraindicated in the presence of:

- necrotic tissue with eschar present;
- untreated osteomyelitis;
- non-enteric and unexplored fistulas;
- malignancy in the wound;
- exposed vasculature;
- exposed nerves;
- exposed anastomotic site; or
- exposed bone or tendons.

[1] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

4. Device Description

We recommend that you identify your device, by the regulation and product code described in section **3. Scope**. We recommend that you provide a comparison between your device and predicate device(s) that provides information on the similarities and differences between your device and predicate device(s). Side by side comparisons, whenever possible, are desirable. We also recommend that you describe how any differences may affect the comparative safety and performance between your device and predicate device(s). In describing your device, we recommend that you provide the following information.

Performance Specifications – Performance specifications should include a description of the suction apparatus, mode of operation, maximum flow rate, and pressure controls. Detailed schematic, assembly, and engineering drawings of the suction apparatus, features, and collection system are recommended in addition to a written description of the apparatus specifications.

Safety Features – Safety features should be designed to aid the physician and patient in safe and effective use of the device. Maximum vacuum pressures that can be generated and maximum flow rate of exudate removal should be constrained to prevent initiation of uncontrolled bleeding or hemorrhage that may result in exsanguination of the patient. Limiting the maximum volume of the collection canister may aid in preventing excessive fluid removal. Safety features, such as filters and alarms or automatic shut-off for full canister, leaks and low battery are recommended.

Accessories – Accessories include single-use items such as dressings, tubing, and canisters. These accessories should be demonstrated to be compatible for use with your device.

5. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the non-powered suction apparatus device intended for NPWT addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. We recommend that you also conduct a risk analysis, before submitting your 510(k), to identify any other risks specific to your device and include the results of this analysis in your 510(k). If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, then you should provide sufficient detail to support the approach you have used to address that risk.

Identified Risk	Recommended Mitigation Measures
Adverse tissue reaction	Section 6. Biocompatibility Section 7. Sterility
Material degradation	Section 8. Stability and Shelf Life

Improper function of suction apparatus (e.g., reflux of waste exudate to wound, incorrect delivery of negative pressure)	Section 9. Performance Testing
Non-compatibility with other therapeutics and diagnostics (e.g., 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 (e.g., improper wound selection, improper wound management, improper placement of dressing)	Section 11. Labeling

6. Biocompatibility

We recommend that wound dressings, tubing and other device components that will come into direct and/or indirect contact with tissues be evaluated for biocompatibility. We recommend you evaluate biocompatibility for these device components as described in the document entitled **Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."**[2] We recommend that you select biocompatibility tests appropriate for the duration and level of patient contact with your device.

Additional biocompatibility testing may be requested if the substrate material is new and has not been previously tested for biocompatibility or if the material is deemed cytotoxic or toxic. For example, if the material is determined to have a cytotoxicity grade higher than Grade 2, animal testing may be requested to demonstrate that the material does not adversely affect wound healing.

7. Sterility

We recommend that wound dressings, tubing and other device components that will come into direct and/or indirect contact with tissues be terminally sterilized. Your submission should indicate the sterilization method, validation method used, and sterility assurance level (SAL) achieved as described in the **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**.[3]

[2] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm.
[3] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm.

8. Stability and Shelf Life

Device components that are not stable and can degrade over time should be labeled with an expiration date and recommended conditions for storage. The labeled expiration date should be supported by appropriate bench tests and sterilization (packaging) validation.

9. Performance Testing

Data collected from performance testing should support the safety and effectiveness of the non-powered suction apparatus device intended for NPWT. Demonstration of safe and effective device performance for the indicated wound types may be demonstrated through bench testing and/or animal studies.

A non-powered suction apparatus device intended for NPWT requires evaluation as a unified system comprising the vacuum generating element, wound interface element(s), and exudate collecting element. Data should demonstrate the ability of the device to maintain user defined or pre-set negative pressure levels at the site of the wound. If the device is capable of producing a range in levels of negative pressure, data should be provided which demonstrates the ability of the proposed device to accurately generate and maintain pressures throughout the available range. The compatibility of the device accessories (dressing, tubing, and canister) with the vacuum source should be demonstrated.

Data should be provided which supports the ability of the device to accurately generate and maintain pressure under usage conditions. This may include testing over extended periods of time and testing pressure signal response to presence and collection of simulated or actual wound exudate as well as environmental operating parameters. When testing with wound exudate, consideration should be taken in regards to viscosity and flow rate.

10. Clinical Information

FDA may recommend that you collect clinical data for a non-powered suction apparatus device intended for negative pressure wound therapy in any of the following cases:

- indications for use dissimilar from a legally marketed system of the same type;
- designs dissimilar from designs previously cleared under a premarket notification; or
- new technology, i.e., technology different from that used in legally marketed low level laser systems for aesthetic use.

FDA will consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale.

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812.

FDA believes that a non-powered suction apparatus device intended for NPWT addressed by this guidance document is a significant risk device as defined in 21 CFR 812.3(m)(4).[4] In addition to the requirement of having an FDA-approved IDE, sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

11. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR Part 801.[5]

Directions for use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we recommend submitting clear and concise instructions that describe the technological features of the specific device and how the device is to be used on patients. Instructions should encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

Addressing risks of device use

Labeling should clearly identify the types and conditions of wounds for which the application of the device are contraindicated. In general, the use of non-powered suction apparatus device intended for NPWT is contraindicated in the presence of:

- necrotic tissue with eschar present
- untreated osteomyelitis
- non-enteric and unexplored fistulas
- malignancy in the wound
- exposed vasculature
- exposed nerves
- exposed anastomotic site
- exposed bone or tendons

Labeling should address the risks associated with the following through adequate warnings and precautions:

---

[4]Information Sheet Guidance, for IRBs, Clinical Investigators, and Sponsors: "Significant Risk and Nonsignificant Risk Medical Device Studies," available at: http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/UCM118082.pdf.

[5]Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

- bleeding and hemorrhage
- hemostasis, anticoagulants, and platelet aggregation inhibitors
- friable vessels and infected blood vessels
- vascular anastomosis
- infected wounds
- osteomyelitis
- exposed organs, vessels, nerves, tendon, and ligaments
- sharp edges (bone fragments)
- dressing being retained in wound
- use in MRI environment
- use in hyperbaric chamber environment
- use with defibrillation
- patient size and weight
- use near vagus nerve (bradycardia)
- patients with spinal cord injury (stimulation of sympathetic nervous system)
- enteric fistulas
- protection of periwound skin
- circumferential dressing application
- intermittent versus continuous pressure
- transmission of infectious agents (standard precautions for infection control per institutional protocol)

Labeling should provide adequate instruction on how to minimize the transmission of infectious agents. Safety features that aid to minimize the transmission of infectious agents should be highlighted. Clear instruction should be provided on how to clean and disinfect any device components that are reusable.

Patient labeling

We recommend that patient labeling be made available in order to ensure safe and effective use of the device if the device is indicated for home care use. In developing patient labeling, you should consult the FDA guidance on medical device patient labeling.[6] The patient labeling should contain information regarding the indications for use, directions for use, and possible adverse reactions written in lay terms for comprehension by the general public. The directions for use should separate what is the responsibility of the patient verse the physician in adequate management of the wound. The patient labeling should also include directions to the patient on how to detect adverse reactions to device use and how to manage adverse reactions. Clinical evaluation or usability testing[7] of the patient labeling is recommended in order to demonstrate that patients can follow the instructions for use, understand the risks of use, and comprehend the measures to be taken in case of adverse reactions to device use.

[6] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm.
[7] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094460.htm.