



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center –WO66-G609
Silver Spring, MD 20993-0002

Spiracur, Inc.
% Ms. Janice Hogan
Regulatory Counsel
Hogan & Hartson LLP
1835 Market Street, Suite 2820
Philadelphia, Pennsylvania 19103

AUG - 7 2009

Re: K081406 SNaP Wound Care Device
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 878.4683
Classification: II
Product Code: OKO

Dear Ms. Hogan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the SNaP Wound Care Device, a prescription device under 21 CFR Part 801.109 that is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. The SNaP Wound Care Device is further indicated for removal of small amounts of exudates from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions and flaps. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the SNaP Wound Care Device, and substantially equivalent devices of this generic type into class II under the generic name, Non-powered suction apparatus device intended for negative pressure wound therapy (NPWT).

FDA identifies this generic type of device as:

“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.”

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the

Department, Inc.
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Re: 5021406 SNAP Wound Care Device
Classification of Automatic Class III Designation
Registration Number 21 CFR 878.4082
Classification II
Product Code: OKO

Dear Ms. Hogan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the SNAP Wound Care Device, a prescription device under 21 CFR Part 801.109 that is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. The SNAP Wound Care Device is further indicated for removal of small amounts of exudates from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions and flaps. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the SNAP Wound Care Device, and substantially equivalent devices of this generic type into class II under the generic name: Non-powered suction apparatus device intended for negative pressure wound therapy.

(SNAP)

FDA identifies this generic type of device as:

"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, tunnels, flaps and grafts."

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 CFR 300.3(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1970 (the date of enactment of the Medical Device Amendments of 1970) (the

amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device type, FDA must publish a notice in the **Federal Register** classifying the device type.

On November 3, 2008, FDA filed your petition requesting classification of the SNaP Wound Care Device into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on October 28, 2008 automatically classifying the SNaP Wound Care Device in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. In order to classify the SNaP Wound Care Device into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device type for its intended use.

After review of the information submitted in the petition, FDA has determined that the SNaP Wound Care Device indicated for patients who would benefit from a suction device particularly as the device may promote wound healing and further indicated for removal of small amounts of exudates from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions and flaps can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type.

In addition to the general controls of the act, the SNaP Wound Care Device is subject to the following special controls: the guidance document entitled, “Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT),” to address the specific risks to health associated with the non-powered suction apparatus device intended for NPWT. The risks identified in the “Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device

...generally referred to as postamendment devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(f) of the act (21 U.S.C. 360c(f)). A premarket device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device type, FDA must publish a notice in the Federal Register classifying the device type.

On September 3, 2008, FDA filed your petition requesting classification of the Z-Wrap. Z-Wrap was classified into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on October 1, 2008, automatically classifying the Z-Wrap Wound Care Device in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1970, nor which was subsequently reclassified into class I or class II. In order to classify the Z-Wrap Wound Care Device into class I or II, it is necessary that the proposed class have sufficient regulatory 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 has determined that the Z-Wrap Wound Care Device indicated for patients who would benefit from a suction device is indicated as the device may promote wound healing and further indicated for removal of small amounts of exudates from chronic, traumatic, surgical, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions and lacerations. Class II special controls provide reasonable assurance of the safety and effectiveness of the device type.

In addition to the general controls of the act, the Z-Wrap Wound Care Device is subject to the following special controls: the guidance document entitled, "Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)", to address the specific risks to health associated with the non-powered suction apparatus device intended for NPWT. The risks identified in the Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device

Intended for Negative Pressure Wound Therapy (NPWT)” are: adverse tissue reaction, material degradation, improper function of suction apparatus, non-compatibility with other therapeutics and diagnostics, uncontrolled bleeding, transmission of infectious agents, and unsafe use of device.

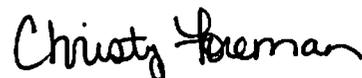
Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this device type and, therefore, the device type is not exempt from the premarket notification requirements of the act. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the non-powered suction apparatus device intended for NPWT they intend to market prior to marketing the device and receive clearance from FDA prior to marketing.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the de novo, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Jiyoung M. Dang, Ph.D. at (240) 276-3555.

Sincerely yours,



Christy Foreman
Deputy Director
for Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

intended for Negative Pressure Wound Therapy (NPWT), and adverse tissue reaction, minimal degradation, improper function of suction apparatus, non-compatibility with other therapies and dressings, uncontrolled bleeding, transmission of infectious agents, and unsafe use of device.

Section 210(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 210(k) of the act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this device type and, therefore, the device type is not exempt from the premarket notification requirements of the act. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the non-powered suction apparatus device intended for NPWT they intend to market prior to marketing the device and receive clearance from FDA prior to marketing.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Devices Management Branch of FDA (5051 Food and Drug Administration, 2030 Fishers Lane, Room 1001, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the device, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Jiyong M. Jiang, Ph.D., at (301) 276-2222.

Sincerely yours,



Christopher Foreman
Deputy Director
for Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health