



Food and Drug Administration
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November 25, 2014

Spiracur Incorporated
% Mr. Ronald S. Warren
Experien Group, LLC
755 North Mathilda Avenue, Suite 100
Sunnyvale, California 94085

Re: K142272

Trade/Device Name: SNaP[®] Wound Care System

Regulation Number: 21 CFR 878.4683

Regulation Name: Non-Powered suction apparatus device intended for
negative pressure wound therapy

Regulatory Class: Class II

Product Code: OKO

Dated: October 21, 2014

Received: October 22, 2014

Dear Mr. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142272

Device Name

SNaP® Wound Care System

Indications for Use (Describe)

The SNaP® Wound Care System is indicated for patients who would benefit from wound management via the application of negative pressure, particularly as the device may promote wound healing through the removal of excess exudate, infectious material and tissue debris. The SNaP® Wound Care System is indicated for removal of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

510(k) Notification K 142272

I. GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Date Prepared: November 21, 2014

II. DEVICE INFORMATION [807.92(a)(2)]

Trade/Proprietary Name:

SNaP[®] Wound Care System

Generic/Common Name:

Negative Pressure Wound Therapy (NPWT) non-powered suction apparatus

Classification Name:

Non-powered suction apparatus device intended for negative pressure wound therapy (21 CFR§878.4683)

Regulatory Class:

Class II

Product Code:

OKO

510(k) SUMMARY (CONT.)

III. PREDICATE DEVICE [807.92(a)(3)]

Spiracur Inc. SNaP[®] Wound Care System (K132080)

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION [807.92(a)(4)]

The SNaP[®] Wound Care System (“SNaP System”) is a non-powered, portable, single-use, disposable Negative Pressure Wound Therapy (“NPWT”) system that is intended for wound management via application of negative pressure to the wound or closed incision for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. The SNaP System is able to generate negative pressure to allow for the removal of wound exudate/fluid from a wound bed or from a closed incision, utilizing dedicated constant-force springs that mechanically generate the negative pressure gradient. The SNaP System has no electrically powered parts and is disposable after use. This 510(k) premarket notification is for design modifications to the 60cc SNaP Cartridge component of the predicate SNaP Wound Care System, in order to introduce a larger capacity 150cc cartridge available with 125mmHg pressure setting.

V. INDICATIONS FOR USE [807.92(a)(5)]

The Indication for Use statement for the SNaP[®] Wound Care System is as follows:

The SNaP[®] Wound Care System is indicated for patients who would benefit from wound management via the application of negative pressure, particularly as the device may promote wound healing through the removal of excess exudate, infectious material and tissue debris. The SNaP[®] Wound Care System is indicated for removal of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.

The proposed SNaP Wound Care System will have the same indications for use statement as the predicate SNaP Wound Care System (K132080), with removal of the phrase “small amounts of” being the sole difference. The SNaP Cartridge subject to this 510(k) clearance is capable of removing and managing up to 150cc of exudate, and as such, will have similar indications for use statement as other legally marketed NPWT systems with comparable exudate management capacity.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [807.92(a)(6)]

This 510(k) premarket notification is for design modifications to the SNaP Cartridge component of the SNaP Wound Care System. There have been no design modifications introduced to any of the SNaP Dressing Kit components of the cleared SNaP Wound Care System (K132080) predicate as a result of the proposed design modifications to the SNaP Cartridge.

510(k) SUMMARY (CONT.)

The proposed larger capacity SNaP Cartridge has been designed to be capable of removing up to 150cc of exudate and is available in a 125mmHg pressure setting. The predicate 60cc capacity SNaP Cartridge is available in 75mmHg, 100mmHg and 125mmHg pressure settings. Both the new SNaP Cartridge subject to this 510(k) and the predicate 60cc capacity SNaP Cartridge will be cleared for use with the SNaP Dressing Kit components of the cleared SNaP Wound Care System (K132080), as listed below:

- SNaP[®] Bridge Dressing Kit
- SNaP[®] Wound Care Dressing Kit (10 cm x 10 cm and 15 cm x 15 cm configurations kitted with off-the-shelf gauze)
- SNaP[®] Foam Dressing Kit (10 cm x 10 cm, 15 cm x 15 cm, and 20 cm x 20 cm configurations)
- SNaP[®] SecurRing

The SNaP Cartridge subject to this 510(k) is substantially equivalent to the predicate SNaP Cartridge, as they have the same intended use in the same wound types, and utilize similar performance specifications and comparable technological features to achieve the same mechanism of action: therefore, the additional capacity does not raise any new issues of safety or effectiveness.

VII. PERFORMANCE DATA [807.92(b)]

All necessary bench testing was conducted on the SNaP System to ensure conformance to design specifications and to support a determination of substantial equivalence to the predicate device.

[807.92(b)(1)]

The nonclinical, bench testing performed included:

- Bench testing conducted to assess the ability of the 150cc capacity SNaP Cartridge to generate 125mmHg \pm 17.5mmHg of negative pressure, including:
 - Multiple cartridge resetting test;
 - Dressing pressure transmission test (after 100x resetting);
 - Dressing pressure transmission test (with fluid injection) when used with a representative worst-case SNaP dressing kit (Bridge Dressing) in a simulated wound model;
- Biocompatibility testing; and
- Packaging and shelf life testing.

[807.92(b)(2)]

No clinical testing was performed in support of this premarket notification.

510(k) SUMMARY (CONT.)

[807.92(b)(3)]

The collective results of the nonclinical testing demonstrate that the materials chosen and the design of the SNaP Wound Care System meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the SNaP Wound Care System does not raise new questions of safety or effectiveness for negative pressure wound therapy when compared to the predicate device.

VIII. CONCLUSIONS

The addition of a 150cc capacity SNaP Cartridge to the SNaP line of NPWT products does not raise any new issues of safety or effectiveness, as both SNaP Systems have the same intended use, have been historically cleared for use in the same wound types, and utilize similar performance specifications and comparable technological features to achieve the same mechanism of action: therefore, the SNaP System as modified is substantially equivalent to the predicate SNaP System (K132080).

The indications for use for the predicate device are substantially equivalent to the proposed indications for use for the SNaP Wound Care System. As demonstrated by successful performance testing, any differences in the technological characteristics between the proposed device and the predicate device do not raise any new issues of safety or effectiveness. Thus, the SNaP Wound Care System is substantially equivalent to the predicate device.

The SNaP[®] Wound Care System device subject of this 510(k) is substantially equivalent to the predicate Spiracur Inc. SNaP[®] Wound Care System (K132080).