



Food and Drug Administration  
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November 19, 2015

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

Re: K151710

Trade/Device Name: SNaP<sup>®</sup> 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 16, 2015  
Received: October 19, 2015

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 Parts 801 and 809); 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)  
K151710

Device Name  
SNaP® Wound Care System

Indications for Use (Describe)  
SNaP System with SNaP Cartridge (60cc):

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 small amounts 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.

SNaP System with SNaP Plus Cartridge (150cc):

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.

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**510(k) Notification K151710**

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

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**Date Prepared: November 19, 2015**

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

**Trade/Proprietary Name:**

SNaP<sup>®</sup> 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

**III. PREDICATE DEVICES [807.92(a)(3)]**

Spiracur Inc. SNaP<sup>®</sup> Wound Care Systems (K142272 and K132080) are cited as predicate devices for this premarket notification.

In addition, to support changes that are the subject of this 510(k), reference is also made to the KCI V.A.C. Therapy System (K120033) and the ciSNaP Closed Incision System (K133137).

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

SNaP<sup>®</sup> Wound Care System

The SNaP<sup>®</sup> 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 based on the concept of forced expansion of volume to produce negative pressure at the wound bed or at the 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. It is capable of delivering negative pressure wound therapy at a near-constant pressure level over several days without any required adjustments by the patient or clinician.

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

SNaP<sup>®</sup> Wound Care System

The Indications for Use statements for the proposed SNaP System with the available cartridges [SNaP Cartridge (60cc), SNaP Cartridge with Reset (60cc), and SNaP Plus Cartridge (150cc)] are identical to those of the respective predicate devices:

- SNaP System with SNaP Cartridge [SNaP Cartridge (60cc) and SNaP Cartridge with Reset (60cc)]

The indications for use for the SNaP System with SNaP Cartridge (60cc) and SNaP Cartridge with Reset (60cc) are identical to those of the predicate SNaP System with SNaP Cartridge (K132080). The Indications for Use are as follows:

“The SNaP<sup>®</sup> 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<sup>®</sup> Wound Care System is indicated for removal of small amounts 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.”

## 510(k) SUMMARY

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- SNaP System with SNaP Plus Cartridge (150cc)

The SNaP System with SNaP Plus Cartridge indications for use are identical to those of the predicate SNaP System with SNaP Plus Cartridge (K142272). The Indications for Use are as follows:

“The SNaP<sup>®</sup> 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<sup>®</sup> 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.”

As such, the proposed device and the predicate devices are substantially equivalent with respect to indications for use.

This 510(k) also includes information to support the removal of a contraindication for use of the SNaP System over actively infected wounds. This labeling modification was supported based on a comparison with other NPWT products that have the same intended use and similar technological characteristics as the proposed device, and are not contraindicated for use with actively infected wounds. Removal of this contraindication was also supported by reference to numerous medical publications that indicated that the risks of use did not clearly outweigh any possible benefit.

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

The predicate SNaP System (K132080) has a 60cc capacity SNaP Cartridge (available in three configurations capable of generating 75mmHg, 100mmHg or 125mmHg of negative pressure) and the predicate SNaP System (K142272) has a 150cc capacity SNaP Plus Cartridge capable of generating 125mmHg of negative pressure. Both predicate devices are used with Spiracur’s dressing kits: SNaP Dressing Kit, SNaP Foam Dressing Kit, and SNaP Bridge Dressing Kit as well as with Spiracur’s SNaP SecurRing accessory.

The proposed device encompasses both cartridge capacity options (i.e., 60cc and 150cc) with the same pressure features as available in the predicate devices. Additionally, the proposed device is available for use with all aforementioned Spiracur dressing kits used by the predecessor predicate devices. The proposed device has minor design differences as compared to the existing Spiracur SNaP Systems predicate devices.

Compared with the SNaP Cartridge cleared with the SNaP System (K132080), the proposed SNaP Cartridge with Reset (60cc) has a more simplified design of the reset feature. The SNaP Cartridge with Reset (60cc) of the proposed SNaP System enables the user to purge air from the cartridge without having to disconnect the tube fitting.

The SNaP Plus Cartridge (150cc) of the proposed device has component modifications as compared to the predicate SNaP Plus Cartridge (K142272). These were minor material or design modifications primarily related to changing the components from prototype scale to commercial scale production.

In addition to the identical dressing kits also used with the predicate systems, the proposed SNaP System incorporates a Long Dressing Kit. The Long Dressing Kit is a version of the commercial SNaP Foam Dressing Kit. The Long Dressing is used in the same way as does the SNaP Foam Dressing, cleared with the predicate SNaP Systems K132080 and K142272.

Finally, the proposed device includes addition of the SNaP Plus Strap which is intended to provide customers with the convenience of an additional product offering to secure the SNaP Plus Cartridge (150cc) to the patient. This optional SNaP Plus Strap is similar to the strap (SNaP Strap) available with the predicate SNaP Cartridge (60cc) (K132080).

### **VII. PERFORMANCE DATA [807.92(b)]**

To support the device modifications covered by this premarket notification, additional testing was performed on the SNaP System to ensure conformance to design specifications and to support a determination of substantial equivalence to the predicate devices.

#### **[807.92(b)(1)]**

The nonclinical, bench testing performed included:

- Device design verification testing at baseline and after 2-years accelerated aging;
- Device user requirements verification for the SNaP Plus Strap;
- Verification testing to support 7-day use of the SNaP cartridges;
- Sterilization validation of the additional dressing kit;
- Biocompatibility testing; and
- Packaging and shelf life testing.

#### **[807.92(b)(2)]**

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

#### **[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 devices.

### VIII. CONCLUSIONS

This 510(k) premarket notification is for minor design changes, labeling modifications and addition of two components (Long Dressing and SNaP Plus Strap) to the SNaP Wound Care System previously cleared under K132080 and K142272. The modifications to the SNaP System do not raise any new issues of safety or effectiveness, as both the proposed device and the predicate devices 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. The proposed Indications for Use statements for the SNaP System is identical to the FDA-cleared Indications for Use statements for the primary predicate devices. The removal of the contraindication for use on actively infected wounds is supported by comparison to labeling of other NPWT devices and published clinical evidence. Any differences in the technological characteristics between the proposed device as compared to the primary predicate devices do not raise any new issues of safety or effectiveness. The SNaP<sup>®</sup> Wound Care System subject of this 510(k) is substantially equivalent to the predicate Spiracur Inc. SNaP<sup>®</sup> Wound Care System cleared under K132080 and K142272.