SECTION 6
510(k) SUMMARY

JUL 21 2011

510(k) Notification K111006

GENERAL INFORMATION

Applicant:

Spiracur Inc.
1180 Bordeaux Drive
Sunnyvale, CA 94089
U.S.A.
Phone: 408-701-5300
Fax: 408-701-5301

Contact Person:

Sarah L. Canio
Experien Group, LLC
155-A Moffett Park Drive, Suite 210
Sunnyvale, CA 94089-1330
U.S.A.
Phone: 408-400-0856
Fax: 408-400-0865
Email: sarah@experiengroup.com

Date Prepared: July 6, 2011

Classification:

21 CFR§878.4683, Class II

Product Code:

OKO

Trade Name:

CI-SNaP™ Wound Care System

Generic/Common Name:

Non-powered suction apparatus device intended for negative pressure wound therapy

Predicate Device:

SNaP™ Wound Care System (K081406)

SECTION 6
510(k) SUMMARY

Intended Use

The CI-SNaP™ Wound Care System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of small amounts of exudates from surgical incisions that continue to drain following sutured or stapled closure.

Product Description

The CI-SNaP Wound Care System is a non-powered, portable, single-use suction device intended for wound management via application of negative pressure to the wound for removal of fluids, including exudate, irrigation fluids and infectious materials. The CI-SNaP Wound Care System is designed to provide active wound treatment to help promote healing in surgical incisions that continue to drain following sutured or stapled closure. The CI-SNaP Wound Care System utilizes dedicated constant-force springs to mechanically generate the negative pressure gradient.

The CI-SNaP™ Wound Care System is used in conjunction with the CI-SNaP™ Dressing Kit.

Substantial Equivalence

The SNaP® System and the CI-SNaP Wound Care System are both non-powered, portable, single-use suction devices intended for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids and infectious materials. Both systems utilize dedicated constant-force springs to mechanically generate the negative pressure gradient. The minor design modifications implemented to develop the CI-SNaP System involve changes to the outer housing and receptacle capacity of the SNaP Cartridge, changes to the activation and deactivation steps, and inclusion of an attachment clip to the CI-SNaP. Additionally, the CI-SNaP Cartridge is provided terminally sterile to enable use of the CI-SNaP System in the operating room suite for the patients with surgically closed incisions. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Therefore, the CI-SNaP Wound Care System is substantially equivalent to the cleared predicate device (K081406).

Testing in Support of Substantial Equivalence Determination

The CI-SNaP Wound Care System and its components were evaluated under design verification tests to assure conformance to design specifications. The nonclinical tests include:

- Bench testing conducted on the CI-SNaP Wound Care System to assess the ability to deliver negative pressure wound therapy
- Biocompatibility testing

Summary

The CI-SNaP Wound Care System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Spiracur
% Experien Group, LLC
Ms. Sarah Canio
155-A Moffett Park Drive, Suite 210
Sunnyvale, California 94089

JUL 2 1 2011

Re: K111006
Trade/Device Name: CI-SNaP™ Wound Care System
Regulation Number: 21 CFR 878.4683
Regulation Name: Non-powered suction apparatus device intended for NPWT
Regulatory Class: II
Product Code: OKO
Dated: July 11, 2011
Received: July 13, 2011

Dear Ms. Canio:

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.

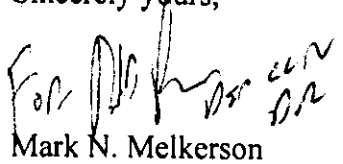
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111006

Device Name: CI-SNaP™ Wound Care System

Indications For Use:

The CI-SNaP™ Wound Care System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of small amounts of exudates from surgical incisions that continue to drain following sutured or stapled closure.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for M&M
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111006