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510(k) Summary
NPWT Foam Dressing Kits

NOV 14 2008

1. **Submitter:** Smith & Nephew, Inc.
970 Lake Carillon Drive, Suite 110
St. Petersburg, FL 33716

2. **Contact:** Laura Krejci
Regulatory Affairs Manager
727-329-7702

3. **Device Name:** NPWT Foam Dressing Kits
Common Name: Powered Suction Pump and Accessories
Classification Name: Powered Suction Pump (21 CFR 878.4780)
Product Classification/Code: Class II, BTA

4. **Predicate Device Information:**

Versatile 1 EZCare Wound Vacuum System BlueSky Medical	510(k) #K061919
Antlia II™ Suction Pump System Innovative Therapies, Inc.	510(k) #K070904

5. **Device Description:**

The NPWT Foam Dressing Kits are a line extension to Smith & Nephew's current Chariker-Jeter™ wound dressing kits. The foam kits are offered in four sizes: small, medium, large and extra-large. In addition to the foam wound dressing, the kits contain a drain and tube to connect to a waste canister and one or more transparent film drapes, depending on kit size. The kits are supplied sterile and are single-use.

The foam is a polyurethane material that is substantially equivalent to other foam dressings currently on the market. The drain and tube materials are silicone or PVC and the drapes are clear polyurethane film; all common materials currently found in similar wound care products.

6. **Intended Use:**

NPWT Foam Dressing Kits are intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) systems to deliver negative pressure to the wound. Smith & Nephew NPWT systems are indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.

NPWT is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/neuropathic ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Explored fistulas
- Skin flaps and grafts

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7. **Substantial Equivalence**

The NPWT Foam Dressing Kits are substantially equivalent in design, materials, technology, function and intended use to the predicate devices named above. Performance testing has been conducted to demonstrate the devices are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

Smith & Nephew, Inc.
% Ms. Laura Krejci
970 Lake Carillon Drive, Suite 110
St. Petersburg, Florida 33716

Re: K082211
Trade/Device Name: Renasys™-F NPWT Foam Dressing Kits
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: October 31, 2008
Received: November 3, 2008

Dear Ms. Krejci:

This letter corrects our substantially equivalent letter of November 14, 2008.

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 (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.

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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

For

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

Enclosure

K082211

Indications for Use

510(k) Number (if known): K082211

Device Name: Renasys™-F NPWT Foam Dressing Kits

Indications for Use:

Renasys™ –F NPWT Foam Dressing Kits are intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) systems to deliver negative pressure to the wound. Smith & Nephew NPWT systems are indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.

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- Explored fistulas
- Skin flaps and grafts

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MAN

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082211