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510(k) Summary
Renasys™ GO Negative Pressure Wound Therapy

FEB 25 2009

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:** Renasys™ GO Negative Pressure Wound Therapy
Common Name: Powered Suction Pump
Classification Name: Powered Suction Pump (21 CFR 878.4780)
Product Classification/Code: Class II, JCX

4. **Predicate Device Information:**

Renasys™ EZ Negative Pressure Wound Therapy System
Smith & Nephew, Inc. 510(k) #K082426
Largo, FL

Antlia II™ Suction Pump System
Innovative Therapies, Inc. 510(k) #K070904
Hunt Valley, MD

Medela® INVIA Liberty Secretion & Surgical Aspirator 510(k) #K080357
Medela AG
Laettichstrasse, Switzerland

5. **Device Description:**

The Renasys GO NPWT device is a lightweight, portable suction device intended to deliver negative pressure to a wound at a range of pressure settings via a tube set connected to a wound dressing. The suction pump creates negative pressure and removes exudates from the wound site to a disposable canister. The device can operate either by a mains power supply or internal battery. Renasys GO is suitable for use in both a hospital and homecare setting and includes a shoulder strap and carry case for portability.

Renasys GO is compatible with existing Smith & Nephew wound dressing kits currently on the market.

6. **Intended Use:**

Renasys™ GO is indicated for patients who would benefit from a suction device (negative pressure) to help promote wound healing by removing fluids including irrigation and body fluids, wound exudates and infectious materials. Examples of appropriate wound types include chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.

7. Substantial Equivalence

In establishing substantial equivalence to the current marketed devices, Smith & Nephew, Inc evaluated the indications for use, materials, technology, product specifications and energy requirements of the currently marketed devices. Performance testing and electrical safety testing has been successfully completed to demonstrate that Renasys GO is substantially equivalent to the marketed devices and is safe and effective for the 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: K083375
Trade/Device Name: Renasys™ GO Negative Pressure Wound Therapy
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: December 22, 2008
Received: December 23, 2008

Dear Ms. Krejci:

This letter corrects our substantially equivalent letter of February 25, 2009.

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K083375

Device Name: Renasys™ GO Negative Pressure Wound Therapy

Indications for Use:

Renasys™ GO is indicated for patients who would benefit from a suction device (negative pressure) to help promote wound healing by removing fluids including irrigation and body fluids, wound exudates and infectious materials.

Examples of appropriate wound types include:

Chronic

Acute

Traumatic

Sub-Acute and dehisced wounds

Ulcers (such as pressure or diabetic)

Partial-thickness burns

Flaps and grafts

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

510(k) Number K083375

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)