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510(k) Summary

AUG - 6 2010

General Information

Submitters Name/Address:

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

Establishment Registration Number: 3006760724

Contact Person: Laura Reynolds
Regulatory Affairs Manager

Phone Number: (727) 329-7702

Date Prepared: August 4, 2010

Device Description

Trade Name: Renasys™ EZ PLUS Negative Pressure Wound Therapy

Generic/Common Name: Powered Suction Pump

Classification Name: Powered Suction Pump; 21 CFR 878.4780
Product Code: OMP

Predicate Device Information

510(k) #	Device	Clearance Date
K091470	Renasys™ EZ	07/09/2009

Device Description

The Renasys EZ PLUS NPWT device is a lightweight, suction device intended for wound management via application of continual or intermittent negative pressure wound therapy to the wound for removal of fluids, including wound exudates, irrigation fluids, and infectious materials. The pump is connected to the wound dressing via a tube connected to a disposable canister. The device provides negative pressure wound therapy to the wound at a range of pressure settings and removes exudates from the wound site to the disposable canister. The device can operate either by a mains power supply or internal battery. Renasys EZ PLUS is suitable for use in either a hospital or homecare setting.

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

Indications for Use

The RENASYS EZ PLUS is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of 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

Non-Clinical Tests (Bench)

Testing in accordance with UL 60601-1 and IEC 60601-1 was conducted for electrical safety.

Testing in accordance with IEC 60601-1-2 was conducted for electromagnetic compatibility.

Testing was conducted to verify the changes in the Renasys EZ PLUS met design specifications and demonstrated substantial equivalence to its predicate device.

Summary of Safety and Effectiveness

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 device. Performance testing and electrical safety testing has been successfully completed to demonstrate that the Renasys EZ PLUS is substantially equivalent to the marketed device and is safe and effective for the intended use.

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

AUG – 6 2010

Smith & Nephew, Inc.
% Ms. Laura Reynolds
Regulatory Affairs Manager
970 Lake Carillon Drive, Suite 110
St. Petersburg, Florida 33716

Re: K102001
Trade/Device Name: Renasys™ EZ PLUS Negative Pressure Wound Therapy
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: July 12, 2010
Received: July 15, 2010

Dear Ms. Reynolds:

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

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Indications for Use

510(k) Number (if known): K102001

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Device Name: Renasys™ EZ Plus

Indications for Use:

The RENASYS EZ PLUS is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of 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

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)

David Krause for NXM
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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