



Food and Drug Administration  
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Smith and Nephew Incorporated  
Ms. Laura Reynolds  
Director Regulatory Affairs  
970 Lake Carillon Drive, Suite 110  
Saint Petersburg, Florida 33716

July 16, 2015

Re: K151326

Trade/Device Name: RENASYS™ EZ PLUS Negative Pressure Wound Therapy Device  
Regulation Number: 21 CFR 878.4780  
Regulation Name: Powered suction pump  
Regulatory Class: Class II  
Product Code: OMP  
Dated: June 23, 2015  
Received: June 24, 2015

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 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,

**Joshua C. Nipper -S**

Binita S. Ashar, M.D., M.B.A., F.A.C.S.

For

Director

Division of Surgical Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

Device Name

RENASYS™ EZ PLUS Negative Pressure Wound Therapy Device

Indications for Use (Describe)

The RENASYS EZ PLUS NPWT 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.

Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Sub-acute and dehisced wounds
- Ulcers (such as pressure or diabetic)
- Partial-thickness burns
- Flaps and grafts

RENASYS EZ PLUS professional healthcare facility model (REF 66800697) is intended for use in acute care settings and other professional healthcare environments where product use is conducted by or under the supervision of a qualified healthcare professional.

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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**Wound Management 727 392-1261**

Smith & Nephew, Inc. F 727 392-6914 or 727 392-0797  
 970 Lake Carillon Drive Customer Care Center: 1 800 876-1261  
 Suite 110 www.smith-nephew.com  
 St. Petersburg, FL 33716

## 510(k) Summary

### 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  
 Director Regulatory Affairs

**Phone Number:** (727) 329-7702

**Date Prepared:** July 16, 2015

### Device Description

**Trade Name:** RENASYS™ EZ PLUS Negative Pressure Wound Therapy Device

**Generic/Common Name:** Powered Suction Pump

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

### Predicate Device Information

Subject Device	Predicate Device	510k#	Clearance Date
RENASYS EZ PLUS Negative Pressure Wound Therapy Device	RENASYS EZ MAX Negative Pressure Wound Therapy Device	K142979	04/29/2015

### Device Description

#### RENASYS EZ PLUS Negative Pressure Wound Therapy Device

The RENASYS EZ PLUS Negative Pressure Wound Therapy (NPWT) device is a lightweight, suction device intended for wound management via application of continuous 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.

The technological characteristics of the subject device have not changed from the predicate device.

### RENASYS Canisters

The 800ml and 250ml canisters are non-sterile, single use devices with a lid that is ultrasonically welded on. The canister kits contain a combination of solidifier gel pack, bacterial overflow guard that attaches to the pump and canister tubing that attaches to the Soft Port assembly.

The 800ml canister without solidifier is a non-sterile, single use device with a lid that is ultrasonically welded on. The canister kit contains a bacterial overflow guard that attaches to the pump and canister tubing that attaches to the Soft Port assembly.

### Indications for Use

#### RENASYS EZ PLUS Negative Pressure Wound Therapy Device

The RENASYS EZ PLUS NPWT 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

Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Sub-acute and dehisced wounds
- Ulcers (such as pressure or diabetic)
- Partial-thickness burns
- Flaps and grafts

RENASYS EZ PLUS professional healthcare facility model (REF 66800697) is intended for use in acute care settings and other professional healthcare environments where product use is conducted by or under the supervision of a qualified healthcare professional.

The indications for Use statement are the same for both devices except the product name and code.

### Summary Comparison between Subject and Predicate Devices

	<b>Subject Device: RENASYS EZ PLUS NPWT</b>	<b>Predicate Device: RENASYS™ EZ MAX NPWT (K142979)</b>
Indications for Use:	Identical	Identical
Components	Substantially equivalent	Substantially equivalent
Principle of Operation	Identical	Identical
Operating Time (Battery)	Identical	Identical
Negative Pressure Range	Identical	Identical
High Flow/Leak Rate Alarm Threshold Limit	Same	Same
Sterilization	N/A	N/A

	<b>Subject Device: RENASYS EZ PLUS NPWT</b>	<b>Predicate Device: RENASYS™ EZ MAX NPWT (K142979)</b>
Biocompatibility	No patient contact materials	No patient contact materials
Software	N/A	N/A
Locking Feature	Identical	Identical
On/Off Switch Protection	Front case protrusions (shrouds) built in the front case on either side of the ON/OFF switch.	Switch protection added to the front of the case on all sides of the ON/OFF switch
Alarm indications	Flashing LED, except the battery failure Solid yellow LED	Solid LED illumination, except the battery charging indicator
	Audible indication	Audible indication modified to comply with 60601-1-8 2nd edition
IV Pole mount	Affixes to IV poles up to 1 ¼" pole diameter.	Redesign to combine IV Pole/Bed Rail Mount. IV Pole Mount will affix to poles up to 2" diameter.
Bed rail mount	Back of device has folding stainless steel bed hooks to fit up to 2 ¼" in diameter.	Redesign to combine IV Pole/Bed Rail Mount. Bed Rail Mount will accommodate bed rails up to 3" in diameter.

#### **RENASYS EZ PLUS NPWT Canisters Only**

	<b>Subject Device: RENASYS EZ PLUS NPWT</b>	<b>Predicate Device: RENASYS EZ MAX NPWT(K142979)</b>
Canisters	Identical	Identical
Bacterial Overflow Guard housing material	Identical	Identical
250ml S-Canister resin	Identical	Identical
800ml S-Canister and (including lid) and 250ml S-Canister lid resin	Identical	Identical
800ml S-Canister; amount of solidifier	Identical	Identical

#### **Non-Clinical Tests (Bench)**

##### RENASYS EZ PLUS Negative Pressure Wound Therapy Device

Testing has been conducted to verify the modifications to the RENASYS EZ PLUS NPWT meet design specifications and demonstrate substantial equivalence to the predicate device.

The list below summarizes the bench testing undertaken and successfully completed for the RENASYS EZ PLUS NPWT device:

- Pumping capacity is equivalent to the predicate device.
- Device provides negative pressure at individual pressure settings, identical to the predicate device.
- Verification that the device delivers negative pressure wound therapy in a continuous and intermittent operating mode identical to the predicate device.
- Verification of Canister Full alarm functionality using wound fluid designed to simulate chemistry and protein content of real exudate.
- Verification of system performance in foreseeable fault conditions.
- Verification of system performance when running with high air leaks at the dressing site
- Verification of system performance in worst case scenarios with ranges of exudate viscosity and protein content.

Device complies with the following standards:

- ISO13485:2003, Medical Devices - Quality Management Systems
- ISO 14971:2012 Medical Devices - Application of Risk Management to Medical Devices
- ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied Part 1: General requirements.(General)
- ISO 15223-2:2010 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied-Part 2: Symbol development, selection and validation. (General)
- BS EN 980:2008 Graphical Symbols for use in the labeling of Medical Devices
- BS EN 1041:2008 +A1:2013 Information Supplied by the Manufacturer with Medical Devices
- IEC 60601-1-2:2007(2<sup>nd</sup> edition) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests, Interpretation Sheet
- IEC 60601-1: :1988 + A1:1991 + A2:1995 Medical Electrical Equipment - Part 1: General Requirements for Safety
- UL 60601-1 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance 1<sup>st</sup> ed.

### **Conclusions**

In establishing substantial equivalence to the predicate devices, Smith & Nephew, Inc. evaluated the indications for use, materials, technology, product specifications and energy requirements of the device. Performance testing has been successfully completed to demonstrate that the RENASYS EZ PLUS NPWT device and canisters are substantially equivalent to the predicate devices for the intended use.