DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 22, 2016

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

Re: K143133
Trade/Device Name: RENASYS™ EZ MAX Negative Pressure Wound Therapy Device, RENASYS™ AB Abdominal Dressing Kit with Soft Port Device
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP, FTL
Dated: June 8, 2015
Received: June 9, 2015

Dear Ms. Reynolds:

This letter corrects our substantially equivalent letter of July 23, 2015.

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143133

Device Name
RENASYS™ EZ MAX Negative Pressure Wound Therapy Device

Indications for Use *(Describe)*
RENASYS EZ MAX 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 MAX professional healthcare facility model (REF 66801309) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143133

Device Name
RENASYS™ AB Abdominal Dressing Kit with Soft Port Device

Indications for Use *(Describe)*
RENASYS AB Abdominal Kit with Soft Port is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary.
It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome.
The use of RENASYS Abdominal Kit with Soft Port is intended for use in acute hospital care settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.

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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We are smith&nephew

Wound Management 727 392-1261

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970 Lake Carillon Drive
Suite 110
St. Petersburg, FL 33716

F 727 392-6914 or 727 392-0797
Customer Care Center: 1 800 876-1261
www.smith-nephew.com

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 1, 2015

Device Description

Trade Name: RENASYS™ EZ MAX Negative Pressure Wound Therapy (NPWT) Device

Generic/Common Name: Powered Suction Pump

Classification Name: Powered Suction Pump; 21 CFR 878.4780

Product Code: OMP

Trade Name: RENASYS™ AB Abdominal Dressing Kit with Soft Port™ Device

Generic/Common Name: Mesh, Surgical Polymeric

Classification Name: Mesh, Surgical Polymeric; 21 CFR 878.3300

Product Code: FTL

Predicate Device Information

Predicate Device	510k#	Clearance Date
RENASYS EZ MAX Negative Pressure Wound Therapy Device	K132446	10/23/2013
RENASYS EZ PLUS Negative Pressure Wound Therapy Device	K102001	08/06/2010
RENASYS AB Abdominal Dressing Kit with Soft Port	K112784	11/22/2011

Predicate Device	510k#	Clearance Date
RENASYS EZ MAX Negative Pressure Wound Therapy Device and RENASYS Foam and Gauze NPWT Wound Dressing Kits with Soft Port	K142979	04/29/2015

Device Description

RENASYS EZ MAX Negative Pressure Wound Therapy Device

The RENASYS EZ MAX 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 new device have not changed.

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.

RENASYS AB Abdominal Dressing Kit with Soft Port

RENASYS AB Abdominal Dressing Kit with Soft Port consists of the following components:

- Two large hydrophobic, reticulated polyurethane foam dressings that incorporate several cuts to facilitate custom sizing, if needed.
- One organ protection layer made of non-adherent clear polyurethane film perforated with slits. The slits in the organ protection layer facilitate fluid removal under negative pressure wound therapy.
- Six 12” x 8” polyurethane transparent film drapes with acrylic adhesive backing. The drapes are placed over the foam and surrounding intact skin to create an airtight seal for the application of negative pressure wound therapy.
- One Soft Port suction assembly with tubing that attaches to the exudate collection canister. The Soft Port assembly is placed over a hole cut in the drape to facilitate application of negative pressure wound therapy to the wound.

The abdominal kit is designed specifically for use with the RENASYS EZ MAX negative pressure wound therapy devices and canisters.

Indications for Use

RENASYS EZ MAX Negative Pressure Wound Therapy Device

The RENASYS EZ MAX 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 MAX professional healthcare facility model (REF 66801309) 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.

RENASYS AB Abdominal Dressing Kit with Soft Port

The RENASYS AB Abdominal Dressing Kit with Soft Port is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome.

The RENASYS AB Abdominal Dressing Kit with Soft Port is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.

Summary Comparison between New and Predicate Devices

RENASYS EZ MAX NPWT

	New Device: **510(k) K143133**	**Predicate Device:** **510(k)# K142979**	**Predicate Device:** **510(k)# K132446**
Trade Name:	**RENASYS EZ MAX NPWT**	**RENASYS EZ MAX Negative Pressure Wound Therapy Device and RENASYS Foam and Gauze NPWT Wound Dressing Kits with Soft Port**	**RENASYS EZ MAX NPWT**
Indications for Use:	Substantially equivalent	Substantially equivalent	Substantially equivalent
Components	Substantially equivalent	Substantially equivalent	Substantially equivalent
Principle of Operation	Identical	Identical	Identical
Operating Time (Battery)	Identical	Identical	Identical

	New Device: **510(k) K143133**	**Predicate Device:** **510(k)# K142979**	**Predicate Device:** **510(k)# K132446**
Trade Name:	**RENASYS EZ MAX NPWT**	**RENASYS EZ MAX Negative Pressure Wound Therapy Device and RENASYS Foam and Gauze NPWT Wound Dressing Kits with Soft Port**	**RENASYS EZ MAX NPWT**
Negative Pressure Range	Identical	Identical	Identical
High Flow/Leak Rate Alarm Threshold Limit	Identical	Identical	Identical
Sterilization	N/A	N/A	N/A
Biocompability	No patient contact materials	No patient contact materials	No patient contact materials
Alarms and Indicators	Identical	Identical	Identical
Software	N/A	N/A	N/A

RENASYS EZ MAX NPWT Canisters Only

	New Device: **510(k) K143133**	**Predicate Device:** **510(k)# K142979**	**Predicate Device:** **510(k)# K102001**
Trade Name:	**RENASYS EZ MAX NPWT**	**RENASYS EZ MAX Negative Pressure Wound Therapy Device and RENASYS Foam and Gauze NPWT Wound Dressing Kits with Soft Port**	**RENASYS EZ PLUS NPWT**
Indications for Use:	Substantially equivalent	Substantially equivalent	Substantially equivalent
Bacterial Overflow Guard	Material change to softer plastic outer casing of filter	Material change to softer plastic outer casing of filter	Plastic outer casing of filter
Material	Substantially equivalent	Substantially equivalent	Substantially equivalent
Canister without solidifier	New	New	N/ A
Canisters with Solidifier	Substantially equivalent	Substantially equivalent	Substantially equivalent

RENASYS AB Abdominal Dressing Kit with Soft Port

	New Device: **510(k) K143133**	**Predicate Device:** **510(k)# K112784**
Trade Name:	**RENASYS AB Abdominal Dressing Kit with Soft Port**	**RENASYS AB Abdominal Dressing Kit with Soft Port**
Indications for Use:	Indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome. This dressing kit is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.	Identical
Materials:	Substantially equivalent	Substantially equivalent
Soft Port Assembly:	Increased aperture size Two slits in paper release liner	Smaller aperture size One slit in paper release liner
Single-use or Reusable:	Single-use	Single-use
Method of Sterilization:	Identical	Identical
Biocompatibility:	All components comply with ISO 10993	All components comply with ISO 10993
Packaging:	Substantially equivalent	Substantially equivalent
Kit Shelf-life	12 months	12 months

Table of Modifications

Modification	Reason For Change	Verification Testing Performed
Modification to the release paper liner of the Soft Port assembly to add an additional slit	Improved usability	Comprehensive verification was completed which demonstrated acceptable device performance and improved usability

Modification	Reason For Change	Verification Testing Performed
Modification to increase the Soft Port aperture size	Improved usability	Comprehensive verification was completed which demonstrated acceptable device performance
Modification of the hole size and geometry in the mid and bottom poly sheet layers of the Soft Port Assembly	Improve manufacturability	Comprehensive verification was completed which demonstrated acceptable device performance and improved usability

Non-Clinical Tests (Bench)

RENASYS EZ MAX Negative Pressure Wound Therapy Device

Testing has been conducted to verify the modifications to the RENASYS EZ MAX 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 MAX NPWT device:

- Pumping capacity is equivalent to the predicate device.
- Device provides negative pressure wound therapy 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.

RENASYS AB Abdominal Dressing Kit with Soft Port

Testing has been conducted to verify the modifications to the RENASYS AB Abdominal Dressing Kit with Soft Port meet design specifications and demonstrate substantial equivalence to the predicate device.

- Verification that the Soft Port serves as a conduit between RENASYS EZ MAX NPWT device and RENASYS AB Abdominal Dressing Kit with Soft Port by transmitting negative pressure wound therapy and collecting exudate flows.
- Verification that the Soft Port functions throughout the recommended maximum elapsed time of 48 hours between dressing changes.

There have been no other changes to patient contacting materials from the predicate devices.

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(3rd 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 60601-1:2005 (3rd edition). Medical Electrical Equipment - Part 1: General Requirements for Safety
- ANSI/AAMI ES60601-1:2005 Version (R2012) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-8:2006 (2nd edition) Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical
- IEC 60601-1-6:2010 (3rd Edition) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366:2007 (1st edition) Medical devices - Application of usability engineering to medical devices. (General)
- ISO 11135: 2014 Medical Devices - Validation and routine control of ethylene oxide sterilization
- ISO 11607-1:2006 Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 10993-7:2008 Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
- ISO 10993-1:2009 Biological evaluation of medical devices Part 1: Evaluation and testing with a risk management process
- AAMI/ANSI HE75:2009 Human Factor Engineering-Design of Medical Devices

Conclusions

In establishing substantial equivalence to the currently marketed predicate 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 MAX NPWT device and canisters, and the RENASYS AB Abdominal Dressing Kit with Soft Port are substantially equivalent to the predicate devices for the intended uses.