



Food and Drug Administration
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August 4, 2016

Smith & Nephew Medical, Ltd.
c/o Ms. Laura Reynolds
Smith & Nephew, Inc.
970 Lake Carillon Dr., Suite 110
St. Petersburg, FL 33716

Re: K153209

Trade/Device Name: RENASYS TOUCH Negative Pressure Wound Therapy, RENASYS TOUCH Canisters, RENASYS TOUCH Carry Bag, Carry Strap, RENASYS Y-Connector, RENASYS TOUCH IV Pole/Bed Clamp, RENASYS TOUCH Class 2 Power Supply

Regulation Number: 21 CFR 878.4780

Regulation Name: Powered suction pump

Regulatory Class: Class II

Product Code: OMP

Dated: July 1, 2016

Received: July 5, 2016

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,

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

Indications for Use

510(k) Number (if known)
K153209

Device Name
RENASYS TOUCH Negative Pressure Wound Therapy Device

Indications for Use (Describe)

RENASYS TOUCH 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

The RENASYS TOUCH 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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510(k) Summary

General Information

Submitters Name/Address: Smith & Nephew Medical
101 Hessle Road
Hull, HU3 2BN
England

Establishment Registration Number: 8043484

Contact Person: Laura Reynolds
Director Regulatory Affairs

Phone Number: (727) 686-8736

Date Prepared: July 18, 2016

Device Description

Trade Name: RENASYS™ TOUCH 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 TOUCH Negative Pressure Wound Therapy Device	RENASYS EZ MAX Negative Pressure Wound Therapy Device (<i>Primary Predicate</i>)	K142979	04/29/2015
RENASYS Y-Connector	Invia Liberty Negative Pressure Wound Therapy System	K142626	06/12/2015

Device Description

RENASYS TOUCH Negative Pressure Wound Therapy Device

The RENASYS TOUCH NPWT device is a lightweight suction pump 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 RENASYS TOUCH NPWT device is designed to deliver negative pressure wound therapy to a closed environment over a wound in order to drain exudates from the wound site to help promote wound healing.

The closed environment over the wound is created by applying a RENASYS sterile foam or gauze wound dressing to the wound site and connecting the sealed wound to the suction pump via a tube that connects to the disposable canister. The suction pump delivers negative pressure wound therapy and removes the exudates from the wound site to the disposable canister.

The device provides negative pressure wound therapy to the wound at a range of pressure settings between 25-200mmHg. The device can operate either by a mains power supply or internal battery.

The RENASYS TOUCH device is compatible with RENASYS Foam and Gauze dressing kits with Soft Port which were cleared under 510(k) K142979.

The RENASYS TOUCH device is also compatible with RENASYS AB Abdominal Dressing Kit with Soft Port cleared under 510(k) K143133.

RENASYS TOUCH is suitable 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 TOUCH Canisters

RENASYS TOUCH uses an integral waste canister that is supplied non-sterile, single-use with a volume capacity of 300ml or 800ml. The waste canister is attached to the pump device by two clips on either side of the canister. The canister is permanently sealed to minimize the potential of users coming into contact with exudates. Safety features include a hydrophobic filter to prevent liquid penetration into the pump, supplemented with an additional filter in the top of the canister as a redundant feature. Each sealed canister contains a solidifier which acts as a gelling agent to the exudate. A 300ml canister without solidifier is also offered.

A tube is permanently attached to the bottom of the waste canister through an inlet port. A connector attached to the distal end of the canister tube attaches to the corresponding tubing included in each Smith & Nephew NPWT dressing kit.

RENASYS Y-Connector

The RENASYS Y-Connector is an accessory device used to connect two wound dressings to one pump. The Y-Connector is compatible with Smith & Nephew RENASYS Foam and Gauze wound dressing kits with Soft Port.

The Y-Connector is constructed of PVC tubing with identical interface connectors as the Soft Port and canister components to which it connects. Performance testing has been completed to demonstrate the device and system functions as intended when used with the Y-Connector.

Indications for Use

RENASYS TOUCH 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

The RENASYS TOUCH 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.

Comparison of Technological Characteristics

The RENASYS TOUCH Negative Pressure Wound Therapy (NPWT) device and canisters that are the subject of this submission are substantially equivalent to the predicate RENASYS EZ MAX Negative Pressure Wound Therapy (NPWT) device and associated canisters. Both devices have the same indications for use, contraindications and fundamental scientific technology. Both devices interface with identical RENASYS Foam and Gauze Dressing Kits and both use disposable canisters for exudate collection. Both devices contain similar alarms.

Primary differences between the devices are the RENASYS TOUCH device is software controlled whereas the RENASYS EZ MAX device is analog controlled. The RENASYS TOUCH device also has a large full-color touchscreen for enhanced user interface during operation.

Performance testing has demonstrated that although the two devices have some technological differences, the performance of the subject device is substantially equivalent to the predicate, and raises no new questions of safety or efficacy.

Summary Comparison between New and Predicate Devices**RENASYS TOUCH NPWT Device and Canisters**

	Subject Device:	Predicate Device: 510(k) #K142979
Trade Name:	RENASYS TOUCH NPWT	RENASYS EZ MAX NPWT
Indications for Use:	Identical	Identical
Principle of Operation	Therapy unit delivers software controlled negative pressure wound therapy to the wound site (continuous and intermittent).	Therapy unit delivers analogue controlled negative pressure wound therapy to the wound site (continuous and intermittent).
Operating Time (Battery)	Up to 16 hours therapy	Up to 40 hours therapy
Negative Pressure Range	25-200mmHg	40-200mmHg
Associated Canisters	300mL canister with solidifier 800mL canister with solidifier 300ml canister without solidifier	250ml Canister with solidifier 800ml Canister with solidifier
User Interface	Full color touchscreen and 3 control buttons	Adjustable pressure selector control knob on front casing; analog vacuum gauge displays pressure setting
Environment of use	Acute care and other professional healthcare environments where product use is conducted by or under the supervision of a qualified healthcare provider	Acute care and other professional healthcare environments where product use is conducted by or under the supervision of a qualified healthcare provider

RENASYS Y-Connector

	Subject Device	Predicate Device 510(k) #142626
	RENASYS Y-Connector	Invia Liberty NPWT System Y-Connector
Indications for Use	Substantially Equivalent	Substantially Equivalent
Materials	Substantially Equivalent	Substantially Equivalent
Single Use or Reusable	Single Use	Single Use
Method of Sterilization	Non-Sterile	Sterile – Method unknown
Biocompatibility	Substantially Equivalent	Substantially Equivalent

Non-Clinical Tests (Bench)

Performance testing has been conducted to verify the RENASYS TOUCH NPWT device meets design specifications and demonstrate substantial equivalence to the predicate devices.

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

- Verification of system performance with full range of RENASYS Foam and Gauze NPWT Dressing Kits with Soft Port and RENASYS AB Abdominal Kit with Soft Port.
- Verification of system performance when operating with two Soft Ports via a Y-connector with both foam and gauze wound fillers.
- Verification of alarms functionality using wound fluid designed to simulate chemistry and protein content of real exudate.
- Verification of system performance with “Intermittent NPWT” mode selected across a range of wound model sizes and pressure settings.
- Verification of system performance in various combinations of challenge conditions.
- Evaluation of battery life of the RENASYS TOUCH at the minimum and maximum available therapy settings.

The software documentation in this submission has been assembled according to the recommendations in the FDA document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, dated May 11, 2005*. The software Level of Concern has been evaluated and determined to be **Moderate**, and appropriate documentation included, as recommended by the cited FDA guidance.

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 1041:2008 +A1:2013 Information Supplied by the Manufacturer with Medical Devices
- IEC 60601-1-2:2014 4th 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) + Am.1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- 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 60601-1-8:2006 (2nd Edition) + Am.1:2012 for use in conjunction with IEC 60601-1:2005 (3rd Edition) + Am.1:2012 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 62366:2007 1st Edition Medical devices - Application of usability engineering to medical devices
- IEC 62304:2006 1st Edition, Medical device software – Software life cycle processes
- AAMI/ ANSI HE75:2009 Human Factor Engineering-Design of Medical Devices
- ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-3 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009)]

Conclusion

In establishing substantial equivalence to the predicate devices, Smith & Nephew evaluated the indications for use, principal of operation, technology, product specifications, energy requirements and materials of the device and accessories. Performance testing, electrical safety testing and software verification has been successfully completed to demonstrate that the RENASYS TOUCH NPWT device and accessories are substantially equivalent to the predicate devices for the intended use.