DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 29, 2016

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

Re: K152163
Trade/Device Name: Renasys Go
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 26, 2016
Received: September 26, 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" (21 CFR 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 on last page

510(k) Number *(if known)*

K152163

Device Name

RENASYS GO Negative Pressure Wound Therapy Device

Indications for Use *(Describe)*

The RENASYS GO 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

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.

We are smith&nephew

Wound Management 727 392-1261

Smith & Nephew, Inc.
970 Lake Carillon Drive
Suite 300
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 300
St. Petersburg, FL 33716

Establishment Registration Number: 3006760724

Contact Person: Laura Reynolds
Director Regulatory Affairs

Phone Number: (727) 686-8736

Date Prepared: September 29, 2016

Device Description

Trade Name: RENASYS™ GO 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 GO Negative Pressure Wound Therapy Device	RENASYS GO Negative Pressure Wound Therapy Device	K083375	02/25/2009

Device Description

RENASYS GO Negative Pressure Wound Therapy Device

The RENASYS GO NPWT device is a modification to predicate device K088375. It 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 GO 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 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 40-200mmHg. The device can operate either by a mains power supply or internal battery.

RENASYS GO Canisters

RENASYS GO uses an integral waste canister that is supplied non-sterile, single-use with a volume capacity of 300ml or 750ml. 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 1.0 micron filter in the top of the canister to resist fluid penetration into the device, as well as a 0.2 micron bacterial filter to prevent the passage of airborne bacteria. Each sealed canister contains a solidifier which acts as a gelling agent to the exudate.

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.

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

Indications for Use

RENASYS GO Negative Pressure Wound Therapy Device

RENASYS GO 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 indications for use of the subject device are identical to the predicate, except "Examples of" has been removed from appropriate wound types.

Comparison of Technological Characteristics

The RENASYS GO Negative Pressure Wound Therapy (NPWT) device and canisters that are the subject of this submission are substantially equivalent to the previously cleared versions of the RENASYS GO Negative Pressure Wound Therapy (NPWT) device and canisters. There has been no change to the indications for use, operating principle, mechanism of action or fundamental scientific technology of the predicate device. Generally, software and hardware modifications were made to improve alarm functionality and to meet IEC 60601 3rd Edition requirements. A 750ml canister has been added as an additional option for highly exuding wounds. Thus the subject and predicate devices have substantially equivalent technological characteristics.

Summary Comparison between New and Predicate Devices

RENASYS GO NPWT

	Subject Device: **510(k)#K152163**	**Predicate Device:** **510(k)# K083375**
Trade Name:	**RENASYS GO NPWT**	**RENASYS GO NPWT**
Indications for Use:	The RENASYS GO 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	The RENASYS GO 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

	Subject Device: **510(k)#K152163**	**Predicate Device:** **510(k)# K083375**
Trade Name:	**RENASYS GO NPWT**	**RENASYS GO NPWT**
	diabetic) • Partial-thickness burns • Flaps and grafts	diabetic) • Partial-thickness burns • Flaps and grafts
Principle of Operation	Same as predicate	Therapy unit delivers software controlled negative pressure wound therapy to the wound site.
Operating Time (Battery)	Same as predicate	20 hours Therapy
Negative Pressure Range	Same as predicate	40-200mmHg
Components	• Therapy unit • 300mL canister • 750mL canister	• Therapy unit • 300mL canister

Table of Modifications

Modification	Reason For Change	Verification Testing Performed
Hardware and Software modifications	To improve alarm functionality	Software validation and comprehensive verification testing was completed which demonstrated acceptable device performance
Software and labeling revisions	IEC 60601 3rd Edition Compliance	Software verification and usability studies were completed which demonstrated acceptable device performance. Electrical safety testing in accordance with IEC 60601 3rd Edition standards has been successfully completed.
Addition of RENASYS GO 750ml canister	Additional option for highly exuding wounds	Comprehensive verification was completed which demonstrated acceptable device performance
Design change to	To improve robustness of	Comprehensive

Modification	Reason For Change	Verification Testing Performed
canister and qualification of alternate materials of construction	device and aid manufacturability	verification was completed which demonstrated acceptable device performance
Markings on canister added to include change indicator	To aid/alert user to appropriate change interval	Usability studies were completed to verify labeling changes

Non-Clinical Tests (Bench)

RENASYS GO Negative Pressure Wound Therapy Device

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

- Pumping capacity is equivalent 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 Complete Blockage/Canister Overcapacity 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.
- Verification of Blockage/Canister Over-capacity & Leak Alarm assertion when used in a vertical orientation.
- Verification of Blockage/Canister Over-capacity & Leak Alarm assertion when used in a horizontal face up orientation.
- Verification of Blockage/Canister Over-capacity & Leak Alarm assertion when used in a horizontal face down orientation.
- Verification of Renasys GO performance at increased heights above the wound.
- Verification of O-Ring durability.

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:

- 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)
- IEC 60601-1:2005 (3rd Edition). Medical Electrical Equipment - Part 1: General Requirements for Safety
- 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) 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 60601-1-11:2010 (1st Edition) Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62366:2007 (1st Edition) Medical devices - Application of usability engineering to medical devices
- ANSI/AAMI ES60601-1:2005 Version (R2012) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- RTCA/DO-160G, Environmental Conditions and Test Procedures for Airborne Equipment, Sections 18, 19, 20.4, 20.5, 21.4, 21.5.
- ANSI/AAMI HE75:2009 Human Factor Engineering-Design of Medical Devices
- IEC CISPR-25 2008, 3rd Ed. Vehicles, Boats and Internal Combustion Engines-Radio Disturbance Characteristics.
- EN 50121-3-2 Part 3-2:2015 Railway Applications Electromagnetic Compatibility

Conclusions

In establishing substantial equivalence to the currently marketed predicate device, 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 GO NPWT device and canisters are substantially equivalent to the predicate devices for the intended use.