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

August 31, 2016

Smith & Nephew, Inc.
Ms. Laura Reynolds
Director, Regulatory Affairs
970 Lake Carillon Drive, Suite 300
St. Petersburg, FL 33716

Re: K162129
Trade/Device Name: RENASYS-G Gauze Dressing Kits with Soft Port
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: July 29, 2016
Received: August 1, 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

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)*
K162129

Device Name
RENASYS-G Gauze Dressing Kits with Soft Port

Indications for Use *(Describe)*

The RENASYS-G Gauze Dressing Kits with Soft Port are intended to be used in conjunction with Smith & Nephew NPWT systems. Smith & Nephew NPWT systems are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via the 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 ordiabetic)
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.

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We are smith&nephew

Wound Management
Smith & Nephew, Inc.
970 Lake Carillon Drive
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St. Petersburg, FL 33716

Customer Care Center: 1 800 876-1261
www.smith-nephew.com

510(k) SUMMARY

General Information

Submitter 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: August 30, 2016

Device Description

Trade Name: RENASYS™-G Gauze
Dressing Kit with Soft Port

Common or Usual Name: Negative Pressure Wound Therapy Powered suction pump

Device Classification: Powered suction pump; 21 CFR 878.4780
Class II

Product Code: OMP

Predicate Device Information

510(k)#	Device	Clearance Date
K142979	RENASYS EZ MAX Negative Pressure Wound Therapy System and RENASYS Foam and Gauze NPWT Wound Dressing Kits with Soft Port	Apr 29, 2015

Device Description

RENASYS Gauze NPWT Wound Dressing Kit with Soft Port

The RENASYS Gauze Wound Dressing Kit with Soft Port consists of the following components:

- Antimicrobial gauze wound filler
- Soft Port assembly
- Non-adherent wound contact layer
- RENASYS Transparent film
- Saline bullet
- No Sting Skin Prep
- Wound ruler

The RENASYS-G Gauze kits are offered in four sizes: small, medium, large and extra-large. The components of the kit are individually packaged and sterilized and kitted in a non-sterile kit package. The kit is single use.

The Soft Port assembly attaches to an exudate canister to deliver negative pressure wound therapy to the wound. The gauze kits are designed specifically for use with the RENASYS negative pressure wound therapy devices and canisters.

Indications for Use

The RENASYS-G Gauze Wound Dressing Kit with Soft Port is intended to be used in conjunction with Smith & Nephew NPWT systems. Smith & Nephew NPWT systems are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via the 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.

Comparison between Subject and Predicate Devices

RENASYS-G Gauze Dressing Kit with Soft Port

	Subject Device:	**Predicate Device:** **510(k)# K142979**
Trade Name:	**RENASYS-G Gauze Dressing Kit with Soft Port**	**RENASYS EZ MAX NPWT and RENASYS Foam and Gauze Dressing Kits with Soft Port**
Indications for Use:	Substantially equivalent	Substantially equivalent
Materials:	Substantially equivalent	Substantially equivalent
Soft Port Assembly:	Substantially equivalent	Substantially equivalent
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:	Individually packaged and sterilized components are kitted into Tyvek pouch. RENASYS Transparent Film lies flat in slightly larger outer Tyvek pouch.	Individually packaged and sterilized components are kitted into Tyvek pouch. RENASYS Transparent Film is folded prior to placing in pouch.
Kit Shelf-life	24 months	9 months
Kit configuration	Identical	RENASYS G - Gauze Dressing Kits with Soft Port, Small, Medium, Large, X-large
Product Codes: Renasys-G Gauze Dressing Kit with Soft Port-Small	66020933	66800933
RENASYS-G Gauze Dressing Kit with Soft Port-Medium	66020934	66800934
RENASYS-G Gauze Dressing Kit		

	Subject Device:	**Predicate Device:** **510(k)# K142979**
Trade Name:	**RENASYS-G Gauze Dressing Kit with Soft Port**	**RENASYS EZ MAX NPWT and RENASYS Foam and Gauze Dressing Kits with Soft Port**
with Soft Port-Large	66020935	66800935
RENASYS-G Gauze Dressing Kit with Soft Port-Extra Large	66020936	66800936

Table of Modifications

Modification	**Reason For Change**	**Verification Testing Performed**
The sterile RENASYS Transparent Film is currently folded prior to being placed in the outer packaging of the kit. The modification is to place the transparent film flat, not folded, into the outer packaging of the kit. This change necessitates increasing the size of the outer packaging.	During routine transit testing, Smith & Nephew identified breaches in the seal of the primary packaging of the Transparent Film specifically in area of the pouch where it is folded.	Transit testing was conducted to assure the sterile barrier of the RENASYS Transparent Film remains intact in the flat configuration
Product codes referenced in the predicate 510(k) (K142979) have been changed	There have been no changes to the kit contents, the product code changes were due to internal business decision.	NA
Extend shelf life from 9 months to 24 months	Shelf life extension	Stability testing and simulated wound model testing on aged product has been conducted to assure acceptance criteria are met.

Non-Clinical Tests (Bench)

RENASYS-G Gauze Dressing Kit with Soft Port

Testing has been conducted to verify the modifications to the RENASYS-G Gauze Dressing Kits with Soft Port meet design specifications and demonstrate substantial equivalence to the predicate device.

- Verification that the change of the configuration of the Renasys Transparent Film in the outer pouch maintains package seal integrity during transit.
- Verification that individually packaged and sterilized components within the kit meet criteria for 24 month shelf life, including meeting performance specifications.

Standards

The device complies with the following standards:

EN ISO 13485:2003 Quality Management Systems - Medical Devices - System requirements for regulatory purposes

EN 1041:2008 +A1 Information Supplied by Manufacturers with Medical Devices

ISO 15223-1:2012 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied.

EN ISO 14971:2012 Medical Devices — Application of Risk Management to Medical Devices

EN ISO 10993-1:2009 Biological evaluation of medical devices-Evaluation and testing with a risk management process

EN 62366:2008: Medical devices - Application of usability engineering to medical devices

Conclusion

In establishing substantial equivalence to the currently marketed predicate device, Smith & Nephew, Inc. evaluated the indications for use, materials, technology and product specifications of the device. Verification testing has been successfully completed to demonstrate that the subject device RENASYS-G Gauze Dressing kits with Soft Port are substantially equivalent to the predicate device for the intended use.