March 21, 2019

Smith & Nephew Medical Limited
% Kulsum Master
Director, Regulatory Affairs
Smith and Nephew
7000 West William Cannon Drive
Austin, Texas 78735

Re: K181822
Trade/Device Name: RENASYS Touch; RENASYS Y-Connector
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: February 18, 2019
Received: February 19, 2019

Dear Kulsum Master:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kimberly Ferlin -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181822

Device Name
RENASYS TOUCH

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 fluids 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

When used with the RENASYS AB Abdominal Kit with Soft Port, RENASYS TOUCH 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.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181822

Device Name
RENASYS Y-Connector

Indications for Use *(Describe)*
The RENASYS Y-Connector can only be used with the RENASYS TOUCH system. 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.
The following wound types may be used with a RENASYS
system that is utilizing a RENASYS Y-connector:
• Flaps and grafts (only in one wound configuration)
• Open abdomen (only in one wound configuration & only with RENASYS TOUCH and RENASYS AB Abdominal Kit)
• Chronic
• Acute
• Traumatic
• Sub-Acute and dehisced wounds
• Ulcers (such as pressure or diabetic)
• Partial-thickness burns

When the RENASYS Y-Connector is used with the RENASYS AB Abdominal Kit with Soft Port (only in one wound configuration), it 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.

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."

510(K) SUMMARY

K181822

General Information

Submitter Name/Address:	Smith & Nephew Medical Limited 101 Hessle Road, Hull HU3 2BN United Kingdom
Establishment Registration Number:	8043484
Contact Person:	Kulsum Master, Director Regulatory Affairs, US Region
Phone Number	+1-512-358-5720
Date Prepared:	July 06, 2018

Application Correspondent:	Smith & Nephew Inc. 7000 West William Cannon Drive, Austin, Texas, 78735, USA
Contact Person:	Kulsum Master, Director Regulatory Affairs, US Region
Phone Number:	+1 512-358-5720

Device Description

Trade Name:	RENASYS TOUCH
Common or Usual Name:	Negative Pressure Wound Therapy powered suction pump
Classification Name:	Powered suction pump (21 CFR 878.4780)
Regulatory Class:	Class II
Product Code:	OMP

Predicate Device Information

510(k) Number:	K153209
Device:	RENASYS TOUCH System
Clearance Date:	August 4, 2016

510(k) Number:	K143133
Device:	RENASYS AB Abdominal Kit
Clearance Date:	July 23, 2015

Device Description

RENASYS TOUCH device is a software controlled suction device consisting of an electric motor driven, diaphragm, vacuum pump. The device is designed to provide Negative Pressure Wound Therapy at a range of pressure settings between 25-200mmHg to a closed environment over one or two wounds. The device removes exudate from the wound site(s) to a disposable container, which may promote wound healing via removal of fluids, including irrigation of body fluids, wound exudates and infectious materials.

RENASYS TOUCH device can be operated by either a mains power supply or internal battery.

RENASYS TOUCH device contains integrated global cellular technology that allows device location, billing and maintenance data to be sent wirelessly to a secure Internet website providing Health Care Professionals access to device information.

The RENASYS TOUCH device is compatible with Smith & Nephew RENASYS Foam, RENASYS Gauze and RENASYS Abdominal dressing kits previously cleared under K152163, K153209 and K143133.

RENASYS TOUCH has also demonstrated compatibility with RENASYS Y-Connector. The RENASYS Y-connector is only intended to be used in conjunction with RENASYS Negative Pressure Wound Therapy (NPWT) systems. The RENASYS Y-Connector can be used to connect one or two wounds through two RENASYS Soft Ports to a single RENASYS TOUCH device. The Y-Connector is constructed of PVC tubing and is compatible with Smith & Nephew RENASYS Foam, RENASYS Gauze and RENASYS Abdominal dressing kits with Soft Port.

Indications for Use – RENASYS TOUCH

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 fluids 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

When used with the RENASYS AB Abdominal Kit with Soft Port, RENASYS TOUCH 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.

Indications for Use – RENASYS Y-Connector

The RENASYS Y-Connector can only be used with the RENASYS TOUCH system. 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.

The following wound types may be used with a RENASYS system that is utilizing a RENASYS Y-connector:

- Flaps and grafts (only in one wound configuration)
- Open abdomen (only in one wound configuration & only with RENASYS TOUCH and RENASYS AB Abdominal Kit)
- Chronic
- Acute
- Traumatic
- Sub-Acute and dehisced wounds
- Ulcers (such as pressure or diabetic)
- Partial-thickness burns

When the RENASYS Y-Connector is used with the RENASYS AB Abdominal Kit with Soft Port (only in one wound configuration), it 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.

Comparison between New and Predicate Device

The technological principal for delivering the negative pressure wound therapy for both the subject and predicate devices are identical. The main differences between the cleared RENASYS TOUCH device K153209 and the subject device are as follows:

a) Introduction of an integrated global cellular technology that allows device location, billing and maintenance data to be sent wirelessly to a secure Internet website providing Health Care Professionals access to device information.

   The wireless technology does not monitor or control the delivery of negative pressure (range -25mmHg to -200mmHg; optimal therapeutic range: -40mmHg to -120mmHg) or transmit patient data.

b) The device software has been updated to facilitate the operation of the wireless technology introduced as part of the 510(k) notice for the subject device, including electronic labelling for wireless regulations.

c) Updated Graphical User Interface (GUI) screen wording when Y-Connector mode to enable to use of the device on one or two wounds when using a Y-connector.

d) The subject device has demonstrated compliance with the Home Healthcare requirements of IEC 60601-1-11.

e) Minor update to the indications for use statement to remove information on use in professional healthcare environments due to the subject device demonstrating compliance to the home healthcare requirements of IEC60601-1-11.

f) The device software has been updated to included video playback with device usage on alarm troubleshooting and canister changes.

g) The device includes compatibility with an additional Class I Power Supply and Power Cords for Hospital Use, purchased separately for special Hospital needs.

h) The indications for use have been updated to clarify that the RENASYS TOUCH pump can be used with the RENASYS AB Abdominal Kit as per the predicate submission K153209. The wording included is taken directly from the indications from the predicate RENASYS AB Abdominal Kit K143133.

Non Clinical Data

Performance testing has been conducted to verify the RENASYS TOUCH device meets the design specifications and demonstrates substantial equivalence to the predicate device. The principle test methods used to demonstrate performance are simulated wound models, using the same test strategy that was used to clear the predicated device. Additional consideration was taken into account regarding function of the wireless communication with the RENASYS TOUCH devices functioning in the same vicinity. All performance testing of the RENASYS TOUCH device was performed in triplicate with devices in close proximity and 3G-GPS enabled.

The list below summarizes the testing undertaken and successfully completed for the RENASYS TOUCH device

- Battery verification over the duration of the RENASYS TOUCH devices' battery life using simulated wound model testing
- Simulated wound model testing to verify the RENASYS TOUCH device maintains pressure at all pressure settings
- Activation and deactivation of the SIM card
- RENASYS TOUCH compatibility testing with the RENASYS Y-Connector in simulated wound models
- Electrical safety testing, Electromagnetic compatibility testing and mechanical/environmental testing to verify its use in transportation, ambulatory and home healthcare environments

Clinical Data

No clinical or animal data is included in this submission

Conclusion

In establishing substantial equivalence to the predicate device, Smith & Nephew Medical Ltd evaluated the indications for use, principle of operation, materials, technology, product specifications and energy requirements of the device. Performance testing, software verification testing, electromagnetic compatibility testing and electrical safety testing has been completed to demonstrate that the RENASYS TOUCH device is substantially equivalent to the predicate device for the intended use.