January 10, 2019

Smith & Nephew Medical Limited
Sam Greenhalgh
Senior Regulatory Affairs Specialist
101 Hessle Road
Hull, HU3 2BN Gb

Re: K181204
Trade/Device Name: RENASYS Y-Connector; RENASYS TOUCH
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: November 30, 2018
Received: December 11, 2018

Dear Sam Greenhalgh:

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)*

K181204

Device Name
RENASYS Y-Connector

Indications for Use *(Describe)*

The RENASYS Y-Connector can only be used with RENASYS TOUCH and RENASYS GO systems.

RENASYS TOUCH and RENASYS GO are 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

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.

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."

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)*
K181204

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 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.

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."

510(k) SUMMARY

K181204

General Information

Submitter Name/ Address:	Smith & Nephew Medical Limited 101 Hessle Road, Hull, HU3 2BN United Kingdom
Establishment registration Number:	8043484
Contact Person:	Sam Greenhalgh, Senior Regulatory Affairs Specialist
Phone Number:	+44 1482 673436
Date Prepared:	May 4th, 2018

Device Description

Trade Name:	RENASYS Y-Connector; RENASYS TOUCH
Common or Usual Name:	Negative Pressure Wound Therapy Suction Pump
Device Classification:	Powered suction pump (21 CFR 878.4780)

Regulatory Class: II

Product Code: OMP

Predicate Device Information

510(k)#	**Device**	**Clearance Date**
K153209	RENASYS Y-Connector (*Primary Predicate*)	August 04, 2016
K151872	Avance Y-Connector S (*Secondary Predicate*)	November 02, 2015
K143133	RENASYS AB Abdominal Dressing Kit with Soft Port Device *(Secondary Predicate)*	July 23, 2015

Device Description

The RENASYS Y-connector is an accessory device to the previously cleared RENASYS TOUCH (K153209) pump for use on one wound only. It is only intended to be used in conjunction with RENASYS Negative Pressure Wound Therapy (NPWT) system which is indicated for patients who would benefit from a suction pump (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 RENASYS Y-Connector can be used to connect one or two wounds of the same etiologies through two RENASYS Soft Ports to a single pump. 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 (it can only be used on one wound with the RENASYS Abdominal dressing kits and only with RENASYS TOUCH).

Indications for Use

The RENASYS Y-Connector can only be used with RENASYS TOUCH and RENASYS GO systems.

RENASYS TOUCH and RENASYS GO are 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

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.

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 of Technological Characteristics

The subject device, RENASYS Y-Connector is substantially equivalent to the primary and secondary predicate devices: RENASYS Y-Connector (K153209) and Avance® Y-Connector S (K151872). The subject and predicate devices have similar indications for use, contraindications and precautions and are intended to be used in conjunction with the same negative pressure wound therapy technology.

The subject device interfaces with RENASYS TOUCH and RENASYS GO NPWT pumps in conjunction with RENASYS Foam, RENASYS Gauze and RENASYS Abdominal Dressing Kits with Soft-Port which use disposable canisters for exudate collection. The technology utilised is the same as for the predicate devices.

Main differences between the subject device and the primary predicate device RENASYS Y-Connector (K153209) is an increase of number of wounds to which the cleared Y-

Connector can be connected i.e. being able to use the Y-Connector on 1 wound to 2 wounds and the inclusion of specific device instructions for use.

To facilitate the use of RENASYS Y-Connector on two wounds with the RENASYS TOUCH device the GUI screen wording and includes a new 'Y-Connector' symbol to the screen when the Y-Connector is being used. This has resulted in a new model number for RENASYS TOUCH; the new code is 66801281.

The Y-Connector cleared as part of K153209 was only cleared for use with RENASYS TOUCH systems. As part of this submission, RENASYS GO will be added as a compatible device.

The Y-Connector cleared as part of K153209 was not cleared for use with the RENASYS AB kit. As part of this submission, RENASYS AB Abdominal kit with Soft Port has been included as a compatible device in a one wound configuration with RENASYS TOUCH.

Comparison between New and Predicate Devices

The Indications for Use statement for the subject device, RENASYS Y-Connector is the same as for the primary predicate device (RENASYS Y-Connector K153209).
The Indications for Use Statement for the primary predicate device will be transferred to the subject device with the addition of a new indication for use on two wounds.

The primary predicate device and the subject of this submission are identical in terms of materials used and technology used.

The main differences between the subject and predicate devices are:

1. Increase in number of wounds, which can be used with RENASYS Y-Connector from one to two wounds.

2. Addition of device specific Instructions for Use Leaflet.

As a consequence of increasing the number of wounds which can be used with the RENASYS Y-Connector from one to two wounds, the following differences can also be observed between the subject and the primary predicate device Indications for Use and Contraindications:

A. Clarification of wound configuration for the following indication for use:
    - Flaps and grafts (only in one wound configuration).

B. Addition of the following indication for use:
    - Open abdomen (only in one wound configuration & only with RENASYS TOUCH & only in a hospital environment)

C. Addition of the following contraindications:
    - Flaps/Grafts in a two wound configuration
    - Open abdomen in a two wound configuration
    - An infected and non-infected wound connected together

Additionally, the RENASYS TOUCH Negative Pressure Wound Therapy device manual has been updated to include use with the RENASYS AB Abdominal Dressing Kit and read as follows:

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.

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.

Non-Clinical Tests (Bench)

The following non-clinical (bench) testing has been carried out:

Simulated Cavity Wound Model Compatibility Testing

- Test results determined that the RENASYS Negative Pressure Wound Therapy (NPWT) system was able to maintain negative pressure within the test requirements (as defined within the acceptance criteria) at the simulated wound bed for a minimum of 95% of the test duration for all test configurations. Testing showed that the use of the subject device, RENASYS Y-Connector does not impact the RENASYS NPWT system performance when tested in conjunction with the cleared RENASYS TOUCH and RENASYS GO NPWT pump devices, RENASYS Foam, RENASYS Gauze and RENASYS Abdominal dressing kits with soft port (only with RENASYS TOUCH) therefore demonstrating product compatibility.

Based on the results, it can be concluded that RENASYS Y-Connector can be used for its intended purposes.

Simulated Cavity Wound Model Testing using Intermittent Therapy Mode

- Test results determined that the RENASYS NPWT system was able to maintain negative pressure within the test requirements (as defined within the acceptance criteria) at the simulated wound bed for a minimum of 95% of the test duration for all test configurations when in intermittent therapy mode. Testing showed that the use of the subject device, RENASYS Y-Connector does not impact the RENASYS NPWT system performance when tested in conjunction with the cleared RENASYS TOUCH and RENASYS GO NPWT pump devices RENASYS Foam and RENASYS Gauze/Foam dressing kits with soft port.

  Based on the results, it can be concluded that RENASYS Y-Connector can be used for its intended purposes.

Simulated Cavity Wound Model Testing using Viscous Simulated Wound Fluid

- Test results determined that the RENASYS NPWT system was able to maintain negative pressure within the test requirements (as defined within the acceptance criteria) at the simulated wound bed for a minimum of 95% of the test duration for all test configurations when using viscous simulated wound fluid and a worst case test device. Testing showed that the use of the subject device, RENASYS Y-Connector does not impact the RENASYS NPWT system performance when using viscous simulated wound fluid and tested in conjunction with the cleared RENASYS TOUCH and RENASYS GO NPWT pump devices and RENASYS Gauze/Foam dressing kits with soft port.

  Based on the results, it can be concluded that RENASYS Y-Connector can be used for its intended purposes.

RENASYS NPWT Pump Battery Characterisation Testing using a Simulated Cavity Wound Model

- Test results determined that the RENASYS NPWT system was able to maintain negative pressure within the test requirements (as defined within the acceptance criteria) at the simulated wound bed for a minimum of 95% of the test duration for all test configurations when in continuous therapy mode. Testing showed that the use of the subject device, RENASYS Y-Connector does not impact the RENASYS TOUCH or RENASYS GO pump device batteries or NPWT system performance when tested in conjunction with the cleared RENASYS TOUCH and RENASYS GO NPWT pump devices and RENASYS/Gauze Foam dressing kits with soft port.
  Based on the results, it can be concluded that RENASYS Y-Connector can be used for its intended purposes.

Alarm Characterisation Testing using a Simulated Cavity Wound Model

- Testing with the Y-Connector, in conjunction with the cleared RENASYS TOUCH and RENASYS GO NPWT pump devices, using RENASYS Foam and RENASYS Gauze dressing kits with soft port demonstrates that both the leak and blockage alarms functioned as intended as defined within the acceptance criteria.
  Based on the results, it can be concluded that RENASYS Y-Connector can be used for its intended purposes.

RENASYS Y-Connector Robustness Testing

- Tensile strength testing showed that none of the RENASYS Y-Connector units came apart when pull forces were applied. All units tested met the acceptance criteria in accordance with ISO 8536-4, Section 6.3 Tensile Strength.
  Based on the results, it can be concluded that the RENASYS Y-Connector can be used for its intended purposes.

Biocompatibility Testing

The RENASYS Y-Connector Assembly has been evaluated according to the Biological Evaluation of Medical Devices Standard BS EN ISO 10993, with particular reference to Part 1 (2009): Evaluation and testing within a risk management process and FDA guidance 'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

The composition of the subject device, RENASYS Y-Connector is identical to that of the primary predicate device, RENASYS Y-Connector (K153209).

The biocompatibility of the RENASYS Y-Connector has been addressed and cleared in 510(k) K153209, August 04, 2016.

Conclusion

In establishing substantial equivalence to the currently marketed predicate device, Smith & Nephew Medical Limited evaluated the indications for use, materials, technology and product specifications of the device. Performance testing and biocompatibility testing assessment testing has been successfully completed to demonstrate that the RENASYS Y-Connector is substantially equivalent to the predicate devices for the intended use.