February 10, 2023

Smith and Nephew Medical Limited
Thomas Robinson
Senior Regulatory Affairs Specialist
101 Hessle Road
Hull, Yorkshire HU3 2BN
United Kingdom

Re: K213853
Trade/Device Name: RENASYS™-WF White Foam NPWT Dressing Small
RENASYS™-WF White Foam NPWT Dressing Large
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 11, 2023
Received: January 17, 2023

Dear Thomas Robinson:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213853

Device Name
RENASYS™-WF White Foam NPWT Dressing Small;
RENASYS™-WF White Foam NPWT Dressing Large

Indications for Use *(Describe)*
The RENASYS White Foam NPWT Dressing is a moist, sterile, polyvinyl alcohol (PVA) foam intended to be used in conjunction with Smith & Nephew RENASYS TOUCH and RENASYS GO Negative Pressure Wound Therapy (NPWT) Systems.

The Smith & Nephew RENASYS system is indicated for patients who would benefit from a suction pump (Negative Pressure Wound Therapy) as it may promote wound healing via the removal of wound fluids, including irrigation of 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
- 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."

510(k) Summary

21 CFR 807.92 (a)(1): Submitter's Information	
510(k) Owner Name	Smith & Nephew Medical Ltd
Address	101 Hessle Road, Hull, HU3 2BN, United Kingdom
Establishment Registration Number	8043484
Contact Name	Thomas Robinson, Senior Regulatory Affairs Specialist
Telephone Number	+44 7985681790
Date Prepared	February 10, 2023
21 CFR 807.92 (a)(2): Device Information	
Device Name (Trade/Proprietary Name)	RENASYS™-WF White Foam NPWT Dressing Small RENASYS™-WF White Foam NPWT Dressing Large
Common Name	Negative Pressure Wound Therapy Powered suction pump
Review Panel	General and Plastic Surgery
Regulation Number	Powered suction pump; 21 CFR 878.4780
Regulatory Class	Class II
Product Code	OMP
21 CFR 807.92 (a)(3): Legally marketed device to which equivalence is claimed	**510(k) Number:** K133276 **Device Name:** V.A.C.® Negative Pressure Wound Therapy System, including the V.A.C.® WHITEFOAM™ Dressing Kits
21 CFR 807.92 (a)(4): Device Description	
RENASYS™-WF White Foam NPWT Dressing for use as a wound filler in conjunction with the RENASYS Touch or GO Negative Pressure Wound Therapy System and compatible components.	

21 CFR 807.92 (a)(5): Indications For Use
The RENASYS™-WF White Foam NPWT Dressing is a moist, sterile, polyvinyl alcohol (PVA) foam intended to be used in conjunction with Smith & Nephew RENASYS TOUCH and RENASYS GO Negative Pressure Wound Therapy (NPWT) Systems. The Smith & Nephew RENASYS NPWT System is indicated for patients who would benefit from a suction pump (Negative Pressure Wound Therapy) as it may promote wound healing via the removal of fluids including irrigation and body fluids, wound exudate 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 • Grafts

21 CFR 807.92 (a)(6): Comparison of Technological Characteristics between the Subject and Predicate Devices
The subject device and predicate device have the same physical and chemical composition; they are both made of foam material Polyvinyl Alcohol (PVA), moistened with water, sterilised by gamma irradiation and share the same dimensions (cm): • 7.5 X 10 X 1 • 15 X 10 X 1

Comparison of the Intended Uses, Indications for use, Wound Types, Contraindications, Kit Components, Materials and Packaging of the Subject and Predicate Devices

Characteristic(s)	**Subject Device:** RENASYS™-WF White Foam NPWT Dressing	**Predicate Device:** V.A.C Whitefoam Dressing	**Comparison Verdict - Substantially Equivalent**
Intended Use	The RENASYS◇ White Foam NPWT Dressing is a moist, sterile, polyvinyl alcohol (PVA) foam intended to be used in conjunction with Smith & Nephew RENASYS TOUCH and RENASYS GO Negative Pressure Wound Therapy (NPWT) Systems. The Smith & Nephew RENASYS system is 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.	The ActiV.A.C., InfoVAC., V.AC. ATS, V.A.C. Freedom, V.A.C. Via, and V.A.C. Simplicity Negative Pressure Wound Therapy Systems are integrated wound management systems for use in acute, extended and home care settings. When used on open wounds, they are Intended to create an environment that - promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. When used on closed surgical incisions, they are also intended to manage the environment of surgical incisions that continue to drain following sutured or -stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy	Yes - The subject device contains the same indications as the predicate device for open wounds. Closed wounds are not listed indications for the subject device. These have different compatible NPWT systems (manufacturer specific).

Indications of Use (Indicated Wound Type)	Appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.	Open wound types include chronic, acute, traumatic, *subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous Insufficiency), flaps and grafts. .	Yes - The Indicated wound types for the subject device are the same as the predicate device except for the predicate device specifically stating Venous insufficiency ulcers, this is not included for the subject device to keep alignment with the compatible RENASYS devices
Contraindications	The use of NPWT and the RENASYS Soft Port is contraindicated in the presence of: • Untreated osteomyelitis • Exposed arteries, veins, organs or nerves • Necrotic tissue with eschar present • Malignancy in wound (with exception of palliative are to enhance quality of life) • Non-enteric and unexplored fistulas • Exposed Anastomotic sites	• **Do not place foam dressings of the V.A.C. Therapy System directly in contact with exposed blood vessels, anastomotic sites, organs or nerves** **NOTE:** Refer to **Warnings** section for additional information concerning **Bleeding**. • V.A.C. Therapy is contraindicated for patients with: o Malignancy in the wound o Untreated osteomyelitis **NOTE:** Refer to **Warnings** section for **Osteomyelitis** information. o Non-enteric and unexplored fistulas o Necrotic tissue with eschar present **NOTE:** After debridement of necrotic tissue and complete removal of eschar, V.A.C. Therapy may be used	Yes - The subject device contains the same contraindications as the predicate device for open wounds
Sterility	Sterilised by Gamma Irradiation	Sterilised by Gamma Irradiation	Yes, same
Packaging	Polyethylene inner and Aluminum foil outer pouch	Polyethylene inner and Aluminum foil outer pouch	Yes, same

Materials	PVA Foam, moistened with water	PVA Foam, moistened with water	Yes, same
Status	Rx Only	Rx Only	Yes – both the subject device and predicate device are prescription only.
Environment of Use	Clinical and Home Environments	Clinical and Home Environments	Yes – both the subject device and predicate device are available for use in clinical and home environments, in line with the respective NPWT system

21 CFR 807.92 (b)(1): Brief discussion of nonclinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence
• Wound model testing in challenge conditions using compatible components • Comparative wound model testing between the subject and predicate device • Testing in accordance with the relevant parts of ISO 10993
21 CFR 807.92 (b)(2): Brief discussion of clinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence
No clinical study conducted or submitted as part of this submission.
21 CFR 807.92 (b)(3): Conclusions drawn
Testing indicates that the subject device performs as intended and on an equivalence basis with the predicate device. The subject device is substantially equivalent to the predicate device with respect to safety and effectiveness.