February 18, 2025

Smith & Nephew Medical Ltd
Ruby Uttley
Senior Regulatory Affairs Specialist
101 Hessle Road
Hull, East Riding of Yorkshire HU3 2BN
United Kingdom

Re: K243576
Trade/Device Name: RENASYS Foam Wound Dressing Kit with AIRLOCK Technology and Soft Port; RENASYS Gauze Wound Dressing Kit with AIRLOCK Technology and Soft Port
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: November 19, 2024
Received: November 19, 2024

Dear Ruby Uttley:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243576

Device Name
RENASYS™ Foam Wound Dressing Kits with AIRLOCK™ Technology and Soft Port
RENASYS™ Gauze Wound Dressing Kits with AIRLOCK™ Technology and Soft Port

Indications for Use *(Describe)*
The RENASYS Foam and Gauze Wound Dressing Kits with AIRLOCK Technology and Soft Port are intended to be used in conjunction with Smith + Nephew traditional Negative Pressure Wound Therapy (tNPWT) RENASYS system.

The Smith + Nephew RENASYS NPWT system is indicated for patients who would benefit from a suction pump (Negative Pressure Wound Therapy), as it allows for wound management 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
- 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.

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510(k) Summary (K243576)

510(k) Summary21 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	Ruby Uttley, Senior Regulatory Affairs Specialist
Telephone Number	+44 7740 531714
Date Prepared	12th Febuary 2025
21 CFR 807.92 (a)(2): Device Information	
Device Name (Trade/Proprietary Name)	RENASYS™ Foam Wound Dressing Kits with AIRLOCK™ Technology and Soft Port RENASYS™ Gauze Wound Dressing Kits with AIRLOCK™ Technology and Soft Port
Common Name	Negative Pressure Wound Therapy Powered Suction Pump
Review Panel	General & Plastic Surgery
Regulation Number	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:** K142979 **Device Name:** RENASYS Foam and Gauze NPWT Wound Dressing Kits with Soft Port
21 CFR 807.92 (a)(4): Device Description	
RENASYS Foam and Gauze Wound Dressing Kits with AIRLOCK Technology and Soft Port are accessories intended for use in conjunction with RENASYS TOUCH, RENASYS GO and RENASYS EDGE Negative Pressure Wound Therapy systems.	
21 CFR 807.92 (a)(5): Intended Use / Indications for Use	
The RENASYS Foam and Gauze Wound Dressing Kits with AIRLOCK Technology and Soft Port are intended to be used in conjunction with Smith + Nephew traditional Negative Pressure Wound Therapy (tNPWT) RENASYS system. The Smith + Nephew RENASYS NPWT system is indicated for patients who would benefit from a suction pump (Negative Pressure Wound Therapy), as it allows for wound management 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
• Grafts

21 CFR 807.92 (a)(6): Comparison of Technological Characteristics between the Subject and Predicate Devices

The subject device is the same as the predicate device in terms of its intended use, indications for use. The difference between the subject device and predicate device is the addition of RENASYS Film with AIRLOCK Technology and Retention Strips. The kit is considered substantially equivalent to the predicate device.

Characteristics	Subject Device: RENASYS Foam and Gauze Wound Dressing Kits with AIRLOCK Technology and Soft Port	Predicate Device: RENASYS Foam and Gauze NPWT Wound Dressing Kits with Soft Port
Intended Use	Same as predicate	Intended to create a closed environment over a wound to allow negative pressure wound therapy to evacuate exudate from the wound into a collection canister
Indications for Use	Same as predicate	Chronic, Acute, Traumatic, Sub-Acute and dehisced wounds, Ulcers (such as pressure or diabetic), Partial-thickness burns, Flaps and Grafts
Kit Components	RENASYS Film with AIRLOCK Technology and Retention Strips replace the RENASYS Transparent Film.	RENASYS Transparent Film, Foam or Gauze, User Manual and other components

	All other components are the same as the predicate device.	

21 CFR 807.92 (b)(1): Brief discussion of nonclinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence

Verification and validation activities conducted demonstrate the subject device continues to perform as intended by handling wound fluids and delivering negative pressure wound therapy. The principal test methods used to demonstrate performance were simulated wound model tests. Non-clinical performance testing was conducted for the determination of substantial equivalence:

- Simulated wound model testing demonstrated the subject device performed as intended
- Human Factors validation study demonstrated safe use by all test subjects
- Biological Evaluation demonstrated subject device is safe for intended use

21 CFR 807.92 (b)(2): Brief discussion of clinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence

No clinical performance data was necessary.

21 CFR 807.92 (b)(3): Conclusions drawn

Based on the non-clinical performance testing provided in this submission, the subject device is substantially equivalent to the legally marketed predicate device (K142979) and there are no different questions of safety or effectiveness.