October 30, 2026

Smith & Nephew Medical, Ltd.
Kerry Greig
Senior Regulatory Affairs Specialist
101 Hessle Rd.
Hull, East Riding of Yorkshire HU3 2BN
United Kingdom

Re: K260306
Trade/Device Name: RENASYS-G 15Fr Channel Drain Gauze Dressing Kit (66802257); RENASYS 15Fr Channel Drain Accessory Kit (66802253)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 29, 2026
Received: January 30, 2026

Dear Kerry Greig:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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)*
K260306

Device Name
RENASYS-G 15Fr Channel Drain Gauze Dressing Kit (66802257)
RENASYS 15Fr Channel Drain Accessory Kit (66802253)

Indications for Use *(Describe)*

The RENASYS Drain Kits are intended to be used in conjunction with Smith+Nephew RENASYS 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 allows for wound management 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

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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"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 Person	Kerry Greig
Telephone Number	+447740531714
Date Prepared	October 29th 2026
21 CFR 807.92 (a)(2): Device Information	
Device Name (Trade/Proprietary Name)	RENASYS-G 15Fr Channel Drain Gauze Dressing Kit (66802257) RENASYS 15Fr Channel Drain Accessory Kit (66802253)
Common Name	Negative pressure wound therapy system
Review Panel	General and 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	K080897
Device Name	VENTURI™ Negative Pressure Wound Therapy System which includes consumable VENTURI™ Gauze Wound Care Set.

21 CFR 807.92 (a)(4): Device Description
The RENASYS-G Drain Gauze Dressing Kit and RENASYS Drain Accessory Kit (15Fr Channel Drain) are intended for use only in conjunction with the Smith & Nephew RENASYS TOUCH Negative Pressure Wound Therapy System. RENASYS Negative Pressure Wound Therapy allows for wound management via removal of fluids, including irrigation and body fluids, wound exudates and infectious materials.

21 CFR 807.92 (a)(5): Intended Use/Indications for use

The RENASYS Drain Kits are intended to be used in conjunction with Smith+Nephew RENASYS 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 allows for wound management 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

Characteristics	Subject Device (K260306)	Predicate Device (K080897)
Indications for Use	The RENASYS Drain Kits are intended to be used in conjunction with Smith+Nephew RENASYS Negative Pressure Wound Therapy (NPWT) Systems. The Smith & Nephew RENASYS NPWT System is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it allows for wound management via the removal of fluids including irrigation and body fluids, wound exudates and infectious materials. Examples of appropriate wound types include: - Chronic - Acute - Traumatic - Sub-Acute and dehisced wounds - Ulcers (such as pressure or diabetic) - Partial-thickness burns - Flaps - Grafts	Use of the Venturi™ Negative Pressure Wound Therapy system is indicated for use for patients with acute or chronic wounds that may be benefited by the application of negative pressure therapy and the potential wound healing effects of removal of fluids including wound exudates, irrigation fluids, body fluids, and infectious materials. Venturi is intended for use in acute care settings only.

Kit Components	Same as predicate except for additional components provided (skin prep barrier wipe, waterproof tape and non-adherent gauze) and the ruler which is not supplied.	NPWT Drain, Connection Tubing, AMD Gauze Roll Transparent Wound Dressing Film, Adhesive Gel Patch Saline

21 CFR 807.92 (b)(1): Brief discussion of nonclinical tests submitted/referenced/relied on in the submission to determine substantial equivalence
Verification activities were conducted which demonstrate the system, with 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 the device was found to have low and acceptable biological risk with respect to the required biocompatibility endpoints.
21 CFR 807.92 (b)(2): Brief discussion of clinical tests submitted/references/relied on in this submission to determine substantial equivalence
No Clinical performance data was provided to support the demonstration of substantial equivalence.
21CFR 807.92 (b) (3): Conclusions drawn from the nonclinical tests
Based on the non-clinical performance testing provided in this submission, the subject device is substantially equivalent to the legally marketed predicate device (K080897) and there are no new questions of safety or effectiveness.