May 27, 2026

Smith & Nephew Medical, Ltd.
Chelsea Baker
Regulatory Affairs Specialist
Contact Address

Re: K260646
Trade/Device Name: RENASYS™ EDGE
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: February 27, 2026
Received: February 27, 2026

Dear Chelsea Baker:

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 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)*
K260646

Device Name
RENASYS™ EDGE

Indications for Use *(Describe)*
The RENASYS™ EDGE Pump is indicated for patients who would benefit from a suction pump (NPWT), as it allows for wound management via removal of fluids, including irrigation fluids 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

The RENASYS™ EDGE Pump is compatible with the following:
• RENASYS™ Foam Dressing Kits
• RENASYS™ Foam Dressing Kit - XL
• RENASYS™ Gauze Dressing Kits
• RENASYS™ Abdominal Dressing Kit
• RENASYS™ Y Connector Kit
• RENASYS™ White Foam Wound Dressing
• RENASYS™ WOUND+ Dressing Kit with AIRLOCK Technology

When used with the RENASYS™ WOUND+ Dressing Kit without filler, the RENASYS™ EDGE pump is indicated for the following additional wound type:
• Closed surgical incisions

Important information when using the RENASYS™ AB Abdominal Kit with Soft Port.
When used with the RENASYS™ AB Abdominal Kit with Soft Port, the RENASYS™ EDGE Pump 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™ AB 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.

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510(k) Summary

21 CFR 807.92 (a)(1): Submitter's Information	
Applicant	Smith & Nephew Medical Ltd
Address	101 Hessle Road, Hull, HU3 2BN, United Kingdom
Establishment Registration Number	8043484
Telephone Number	+44 (0)7793553737
Contact Person	Chelsea Baker
Date Prepared	30th April 2026
21 CFR 807.92 (a)(2): Device Information	
Device Name	RENASYS ™ EDGE
Common Name	Negative Pressure Wound Therapy System
Classification Name	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	K231939
Device Name	RENASYS™ EDGE

21 CFR 807.92 (a)(4): Device Description

The RENASYS™ EDGE 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 allows for wound management via removal of fluids, including irrigation of body fluids, wound exudates and infectious materials.

The RENASYS ™ EDGE Negative Pressure Wound Therapy Pump can be operated by either a mains power supply or internal battery.
The RENASYS ™ EDGE device is compatible with Smith & Nephew RENASYS ™ Dressing Kits.

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

The RENASYS ™ EDGE Pump 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 fluids 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

The RENASYS ™ EDGE Pump is compatible with the following:

- RENASYS™ Foam Dressing Kits
- RENASYS™ Foam Dressing Kit – XL
- RENASYS™ Gauze Dressing Kits
- RENASYS™ Abdominal Dressing Kit
- RENASYS™ Y Connector Kit
- RENASYS™ White Foam Wound Dressing
- RENASYS™ WOUND+ Dressing Kit with AIRLOCK™ Technology

When used with the RENASYS ™ WOUND+ Dressing Kit without filler, the RENASYS ™ EDGE pump is indicated for the following additional wound type:

- Closed surgical incisions

When used with the RENASYS™ AB Abdominal Kit with Soft Port, the RENASYS ™ EDGE pump 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 ™ AB 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

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

The RENASYS ™ EDGE device was previously cleared under K231939, whereby the application was to add the RENASYS™ White Foam dressing kits as compatible devices. No significant changes have been made to the subject device since this clearance; a summary of the similarities and differences are included below:

Characteristics	Subject Device	Predicate Device (K231939)	Comparison
Trade Name	RENASYS ™ EDGE	RENASYS ™ EDGE	
Intended Use	Intended to create a closed environment over a wound to allow negative pressure wound therapy to evacuate from the wound into a collection canister.	Intended to create a closed environment over a wound to allow negative pressure wound therapy to evacuate from the wound into a collection canister.	Same as predicate
Indications for Use	Appropriate wound types include: • Chronic • Acute • Traumatic • Sub-acute and dehisced wounds • Ulcers (such as pressure or diabetic) • Partial-thickness burns • Flaps • Grafts When used with the RENASYS ™ WOUND+ Dressing Kit without filler; the RENASYS ™ EDGE pump is indicated for the following additional wound type: • Closed surgical incisions	Appropriate wound types include: • Chronic • Acute • Traumatic • Sub-acute and dehisced wounds • Ulcers (such as pressure or diabetic) • Partial-thickness burns • Flaps • Grafts	Same as predicate with the addition of RENASYS ™ WOUND+ Dressing Kit without filler indication – Indication cleared in K251826
Compatible Devices	• RENASYS ™ Foam Dressing Kits K142979	• RENASYS ™ Foam Dressing Kits K142979	Same as predicate with the addition of RENASYS™ WOUND+ Dressing Kit

	• RENASYS ™ Foam Dressing Kit – XL K202783 • RENASYS ™ Gauze Dressing Kits K142979 • RENASYS ™ Abdominal Dressing Kit K14133 • RENASYS ™ Y Connector Kit K181822 • RENASYS ™ White Foam Wound Dressing K213853 • RENASYS ™ WOUND+ Dressing Kit with AIRLOCK™ Technology K243576	• RENASYS ™ Foam Dressing Kit – XL K202783 • RENASYS ™ Gauze Dressing Kits K142979 • RENASYS ™ Abdominal Dressing Kit K14133 • RENASYS ™ Y Connector Kit K181822 • RENASYS™ White Foam Wound Dressing K213853	with AIRLOCK ™ Technology cleared under K243576
Mode of Action	Negative Pressure Wound Therapy	Negative Pressure Wound Therapy	Same as predicate
Device Operation	Software	Software	Same as predicate
User Interface	Utilizes tactile buttons with soft key function	Utilizes tactile buttons with soft key function	Same as predicate
Single-use or Reusable	Reusable pump unit, Disposable canister	Reusable pump unit, Disposable canister	Same as predicate
Method of Sterilization	Non-sterile	Non-sterile	Same as predicate
O-Ring	Incorporates O-ring on the canisters allowing for a new O-ring with each therapy	Incorporates O-ring on the canisters allowing for a new O-ring with each therapy	Same as predicate
Battery type	Lithium Ion	Lithium Ion	Same as predicate
Negative Pressure	25-200mmHg	25-200mmHg	Same as predicate
Therapy Mode	Continuous & Intermittent	Continuous & Intermittent	Same as predicate
Alarms	Device utilizes alarms to notify the user of any loss of therapy	Device utilizes alarms to notify the user of any loss of therapy	Same as predicate
Auto Restart	Incorporates an auto-restart function to re-initiate therapy if the device has been left on pause for more than 1 hour	Incorporates an auto-restart function to re-initiate therapy if the device has been left on pause for more than 1 hour	Same as predicate
Wireless Technology	Incorporates wireless technology to allow for Bluetooth connectivity	Incorporates wireless technology to allow for Bluetooth connectivity	Same as predicate

Configurations	300ml & 800ml canisters available	300ml & 800ml canisters available	Same as predicate
Accessories			
Carry Bag	Carry bag for use with device and 300ml Canister	Carry bag for use with device and 300ml Canister	Same as predicate
Carry Strap	Carry strap fixes to carry handle	Carry strap fixes to carry handle	Same as predicate

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 overall system performance of the RENASYS ™ EDGE Negative Pressure Wound Therapy System.

Performance testing for the use of RENASYS™ WOUND + is covered within the K243576 and K251826 submissions.

Verification activities were conducted which demonstrate the overall system performance of the RENASYS ™ EDGE device is not impacted by the cumulative updates to the RENASYS ™ EDGE NPWT System. The principal test methods used to demonstrate performance were simulated wound model tests to ensure satisfactory performance and substantial equivalence to the predicate device.

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 necessary to support the demonstration of substantial equivalence to the predicate device.

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 (K231939) and there are no new questions of safety or effectiveness.