May 24, 2024

Smith & Nephew Medical Ltd
Ruby Uttley
Senior Regulatory Affairs Specialist
101 Hessle Road
Hull, East Riding of Yorkshire HU32BN
United Kingdom

Re: K231939
Trade/Device Name: Renasys Edge
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 1, 2023
Received: April 25, 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.

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 Infection Control
and 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)*
K231939

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 may promote wound healing 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 accessory dressing kits:

- 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

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	
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
Telephone Number	+447890 426317
Date Prepared	May 24 2024
21 CFR 807.92 (a)(2): Device Information	
Device Name (Trade/Proprietary Name)	RENASYS™ EDGE
Common Name	Negative pressure wound therapy system
Review Panel	General and Plastic Surgery
Regulation Number	21 CFR 878.4783
Regulatory Class	Class II
Product Code	OMP
21 CFR 807.92 (a)(3): Legally marketed device to which equivalence is claimed	**510(k) Number:** K223041 **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 may promote wound healing via removal of fluids, including irrigation of body fluids, wound exudates and infectious materials. RENASYS™ EDGE 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 may promote wound healing 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 accessories:

- 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

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 in K223041 with a range of dressing kits. The subject of this application is to add the RENASYS™ White Foam dressing kits as compatible devices (cleared in K213853). No changes have been made to the predicate device to allow for use with the RENASYS™ White Foam dressing kits. A summary of the similarities and differences is included below.

	Predicate Device (K223041)	Subject Device (K231939)	Comparison
Trade Name:	**RENASYS™ EDGE**	**RENASYS™ EDGE**	
Intended Use	Same as subject device	Per intended use section	Same
Compatible Devices	RENASYS™ Foam Dressing Kits K142979 RENASYS™ Foam Dressing Kit – XL K202783 RENASYS™ Gauze Dressing Kits K142979 RENASYS™ Y Connector Kit K181822 RENASYS™ Abdominal Dressing Kit K143133 (The only kit for use in an open abdomen)	RENASYS™ Foam Dressing Kits K142979 RENASYS™ Foam Dressing Kit – XL K202783 RENASYS™ Gauze Dressing Kits K142979 RENASYS™ Y Connector Kit K181822 RENASYS™ Abdominal Dressing Kit K143133 (The only kit for use in an open abdomen) RENASYS™ WF White Foam Wound Dressing K213853	Same except the addition of RENASYS™ White Foam per the scope of this submission. For both the subject and predicate devices, the only kit for use with an open abdomen is the RENASYS™ Abdominal Dressing Kit
Mode of Action	Negative Pressure Wound Therapy	Negative Pressure Wound Therapy	Same
Device Operation	Software	Software	Minor updates to Software and Firmware to resolve anomalies
User Interface	Utilizes tactile buttons with soft key function	Utilizes tactile buttons with soft key function	Same
Single-use or Reusable:	Reusable pump unit, Disposable canister	Reusable pump unit, Disposable canister	Same

Method of Sterilization:	Non-Sterile	Non-Sterile	Same
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
Battery type	Lithium Ion	Lithium Ion	Same
Negative Pressure	25-200mmHg	25-200mmHg	Same
Therapy Mode	Continuous & Intermittent	Continuous & Intermittent	Same
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
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
Wireless Technology	Incorporates wireless technology to allow for Bluetooth connectivity	Incorporates wireless technology to allow for Bluetooth connectivity	Same
Configurations	300ml & 800ml canisters available	300ml & 800ml canisters available	Minor manufacturing updates to pump and canisters
Accessories			
Carry Bag	Carry bag for use with device and 300ml Canister	Carry bag for use with device and 300ml Canister	Same physical product; labels modified to clarify country of origin as USA, as well as removal of unnecessary European regulatory symbols.
Carry Strap	Carry strap fixes to carry handle	Carry strap fixes to carry handle	Same physical product; labels modified to clarify country of origin as USA, as well as removal of unnecessary European regulatory symbols.

A range of minor modifications were made to the subject device when compared to the predicate device summarized below:

Technology Changes

- Software and firmware updates to resolve anomalies and update anomaly list
- Updates to pump to enhance manufacturability of the device, including addition of exhaust component, a change of material for the foam inside the exhaust box, addition of a label overlay, and addition of an adhesive bead to the interface between the lens and the top trim
- Updates to canisters, including addition of an odor filter, updating the assembly process so the SAP bag within the canister is no longer attached to the post, and change of the SAP gelling agent weight to 3g to the 300 mL canister

Labeling Changes

- Updated package labeling to include modifications to the EDGE canister, EDGE carry bag and EDGE carry strap labels
- Minor updates to the EDGE manuals for clarity
- Addition of magnetic safety information
- Addition of cleared, compatible accessories to the Indications for Use (updated in EDGE manuals)
- Additional EMC User Environment Table for aircraft environment use

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

Verification activities were conducted which demonstrate the overall system performance of the RENASYS^{TM} EDGE device is not impacted by the use of RENASYS^{TM} White Foam. The principal test methods used to demonstrate performance were simulated wound model tests to ensure satisfactory performance including fluid management and Negative Pressure Wound Therapy (NPWT) delivery.

- Simulated wound model tests to ensure satisfactory performance including fluid management and Negative Pressure Wound Therapy (NPWT) delivery

- EMC Testing in accordance with IEC 60601-1-2 and RTCA DO-160G
- Cybersecurity testing in accordance with FDA guidance "Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff"
- Software design and testing in accordance with the framework set out in IEC 62304:2006
- To support the new environment for use (aircraft), EMC testing (RTCA DO-160G) and NPWT wound model testing was carried out in a low air pressure environment

21 CFR 807.92 (b)(2): Brief discussion of clinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence
No clinical data was provided to support the demonstration of substantial equivalence.
21 CFR 807.92 (b)(3): Conclusions drawn
In establishing substantial equivalence to the predicate device, Smith & Nephew Medical Ltd evaluated the indications for use, principle of operation, materials, technology, product specifications and energy requirements of the device. Performance testing has been completed to demonstrate that the RENASYS^{TM} EDGE device when used with the RENASYS^{TM} White Foam is substantially equivalent to the predicate device for the intended use.