November 22, 2022

Smith & Nephew Medical Limited
Zoe Smith
Regulatory Affairs Specialist
101 Hessle Road
Hull, HU3 2BN
United Kingdom

Re: K223041
Trade/Device Name: Renasys Edge (66803126)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 29, 2022
Received: September 29, 2022

Dear Zoe Smith:

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 Morabito, PhD
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)*
K223041

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

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.

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510(k) Summary (K223041)

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	Zoe Smith
Telephone Number	+447583672659
Date Prepared	November 21st 2022
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:** K181822 **Device Name:** RENASYS TOUCH
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 (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

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 is the next generation in the existing RENASYS family. While there are minor technological differences between the RENASYS EDGE device and predicate device, they have the same requirements and capability with respect to exudate management, therapeutic pressure setting, and operating principles. There minor differences between the devices are to enhance the user experience and do not raise any new or different questions of safety and effectiveness.

	Predicate Device (K181822)	Subject Device (K223041)	Comparison
Trade Name:	**RENASYS TOUCH**	**RENASYS EDGE**	
Intended Use:	Same as subject device	Per intended use section	Same, aside from minor formatting change
Mode of Action	Negative Pressure Wound Therapy	Negative Pressure Wound Therapy	Same
Device Operation	Software	Software	Same
User Interface	Utilizes a touch screen and tactile buttons	Utilizes tactile buttons with soft key function	Different, but with no impact to therapy
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 device	Incorporates O-ring on the canisters allowing for a new O-ring with each therapy	Similar
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	N/A	Incorporates an auto-restart function to re-initiate therapy if the device has been left on pause for more than 1 hour	Different, with the subject device providing an enhanced user experience
Wireless Technology	Utilizes wireless data (3G) to enable device tracking	Incorporates wireless technology to allow for Bluetooth connectivity	Different, but with no impact to therapy
Configurations	300ml & 800ml canisters available	300ml & 800ml canisters available	Same
Accessories			
Carry Bag	Carry bag for use with device and 300ml Canister	Carry bag for use with device and 300ml Canister	Same
Carry Strap	Carry strap fixes to carry strap mounts	Carry strap fixes to carry handle	Similar

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 EDGE device. The principal test methods used to demonstrate performance were simulated wound model tests. • Electrical safety per IEC 60601-1 and IEC 60601-1-11 (home use) • EMC per IEC 60601-1-2 • Human factors per IEC 62366, IEC 60601-1-6 and applicable guidelines listed in FDA Guidance Document: Applying Human Factors and Usability Engineering to Medical Devices (FDA 2011-D0469) • Bench top performance testing including challenge conditions

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 were 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, software verification testing, electromagnetic compatibility testing and electrical safety testing has been completed to demonstrate that the RENASYS EDGE device is substantially equivalent to the predicate device for the intended use.