January 14, 2022

Smith & Nephew Medical Limited
Steeve Lamvohee
RA Director
101 Hessle Road
Hull, Yorkshire HU3 2BN
United Kingdom

Re: K202783
Trade/Device Name: Renasys-F XL Foam Dressing Kit With Soft Port, Renasys XL Transparent Film Dressing
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 23, 2021
Received: September 27, 2021

Dear Steeve Lamvohee:

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, Ph.D.
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)*
K202783

Device Name
RENASYS-F XL Negative Pressure Wound Therapy Foam Dressing Kit with Soft Port
RENASYS XL Transparent Film Dressing

Indications for Use *(Describe)*
RENASYS-F Foam dressing kits with Soft Port and RENASYS Films are intended to be used in conjunction with Smith & Nephew RENASYS Negative Pressure Wound Therapy (NPWT) Systems.

The Smith & Nephew RENASYS system 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 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.

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510(k) Summary K202783

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	Dr Steeve Lamvohee, Regulatory Affairs Director
Telephone Number	+44 7583 048727
Date Prepared	13th January 2022
21 CFR 807.92 (a)(2): Device Information	
Device Name (Trade/Proprietary Name)	RENASYS-F XL Negative Pressure Wound Therapy Foam Dressing Kit with Soft Port RENASYS XL Transparent Film Dressing
Common Name	Negative Pressure Wound Therapy foam kit Negative Pressure Wound Therapy films
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:** K142979 **Device Name:** RENASYS-F Negative Pressure Wound Therapy Foam Dressing Kits with Soft Port
21 CFR 807.92 (a)(4): Device Description	
The RENASYS-F XL Negative Pressure Wound Therapy (NPWT) Foam Dressing Kit with Soft Port is a sterile, single use device containing one extra-large polyurethane foam wound filler sheet (18.9in x 16.1in x 0.6in / 48cm x 41cm x 1.5cm), one soft port and six transparent films (12in x 8in / 30cm x 20cm). The RENASYS XL Transparent Film Dressing is a sterile, single use device provided in a pack containing five transparent films (15in x 24in / 38cm x 60cm). The RENASYS XL Transparent Film Dressing are provided where additional film dressings may be needed to supplement other RENASYS dressing kits. The RENASYS-F XL Negative Pressure Wound Therapy Foam Dressing Kit with Soft Port and RENASYS XL Transparent Film Dressing are intended to be used in conjunction with	

Smith & Nephew RENASYS Negative Pressure Wound Therapy (NPWT) systems and dressing kits.
These devices are compatible with the RENASYS TOUCH NPWT pump (cleared in K181822) and RENASYS GO NPWT pump (cleared in K152163).

The devices for which clearance is being sought are:
RENASYS-F XL Negative Pressure Wound Therapy Foam Dressing Kit with Soft Port
Containing cleared components (soft-port and transparent film) and a larger sized foam sheet consisting of identical material to the foam sheets in the predicate device
RENASYS XL Transparent Film Dressing
a larger sized transparent film of identical material to the film sheets in the predicate device

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

RENASYS-F Foam dressing kits with Soft Port and RENASYS Films are intended to be used in conjunction with Smith & Nephew RENASYS Negative Pressure Wound Therapy (NPWT) Systems.

The Smith & Nephew RENASYS system 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 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 and predicate device have identical indications for use, similar technological characteristics and the same principles of operation. The minor technological difference in the dimensions of the foam and transparent film does not raise any new or different questions of safety and effectiveness compared to the predicate device. The changes made to the Soft Port from the predicate device specifically relate to the release handles and the controlled leak pathway, and do not impact the safety or effectiveness.

The subject device and the predicate device are based on the following same technological elements:

- The devices are single patients use, supplied sterile and disposable
- The devices have the similar design and utilise the same materials of construction

- The devices are connected to a negative pressure pump via the RENASYS Soft Port

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-F XL Foam Kit and RENASYS XL Film. The principal test methods used to demonstrate performance were simulated wound model tests.

- Wound model tests demonstrating performance of RENASYS-F XL Foam Kit and RENASYS XL Film when used with RENASYS GO and RENASYS TOUCH NPWT pumps at various pressures, minimum/maximum leak rates and use in combination with cleared RENASYS consumables
- Wound model testing demonstrating no change in performance between large and extra-large wound sizes
- Wound model tests demonstrating RENASYS GO and RENASYS TOUCH NPWT leak and blockage alarms are not impacted when used with RENASYS-F XL Foam Kit and RENASYS XL Film
- Physical testing on the XL Foam (tensile strength, elongation at break, loss on drying)
- Physical testing on the XL Transparent Film Dressing (Moisture Vapor permeability, Waterproofness, Adhesion to Steel, Tensile strength, Weight of Adhesive (g/m^2), Weight of Base Film (g/m^2), Extensibility, Permanent Set)

RENASYS-F XL Foam Kit and RENASYS XL Film meets the biocompatibility requirements of:

- FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995.
- International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The biological endpoints for the subject devices are in line with the requirements of ISO 10993 with consideration to: Cytotoxicity, Sensitization, Irritation, Material mediated pyrogenicity, Systemic toxicity (acute, sub-acute and sub-chronic) and Implantation
- Evaluation and risk assessment of bacterial endotoxin contamination in accordance with ANSI/AAMI ST72:2019

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

Based on the test results and the additional supporting information provided in this submission, S+N believe the subject device is substantially equivalent to the legally marketed predicate device. To the extent that where there are differences between the subject device and the predicate device, these differences do not raise new or different questions of safety or effectiveness.