January 5, 2022

Smith Nephew Medical Limited
Steeve Lamvohee
Director, Regulatory Affairs, Advanced Wound Management
101 Hessle Road
Hull, Yorkshire HU3 2BN
United Kingdom

Re: K211318
Trade/Device Name: PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System, PICO Fluid Management Packs
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: August 18, 2021
Received: August 19, 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)*
K211318

Device Name
PICO 7 Single Use Negative Pressure Wound Therapy System
PICO 14 Single Use Negative Pressure Wound Therapy System
PICO Fluid Management Packs

Indications for Use *(Describe)*
PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System and PICO Fluid Management Packs are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
  - o Venous Leg Ulcers – PICO can be used in combination with Graduated Compression Therapy in the management of Venous Leg Ulcers
- Flaps and grafts
- Closed surgical incisions

PICO 7 Single Use Negative Pressure Wound Therapy Systems, PICO 14 Single Use Negative Pressure Wound Therapy Systems and PICO Fluid Management Packs are suitable for use in both a hospital and homecare setting.

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 – K211318 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
Date Prepared	December 10, 2021
21 CFR 807.92 (a)(2): Device Information	
Device Name (Trade/Proprietary Name)	PICO 7 Single Use Negative Pressure Wound Therapy System PICO 14 Single Use Negative Pressure Wound Therapy System PICO Fluid Management Packs
Common Name	Negative Pressure Wound Therapy Powered Suction Pump
Review Panel	General & 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:** K202157 **Device Name:** PICO 7 Single Use Negative Pressure Wound Therapy System

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

The PICO 7 and PICO 14 Single Use Negative Pressure Wound Therapy Systems consist of:

- PICO Pump
- Batteries
- PICO Dressing (s)
- Instructions for Use
- Fixation Strips

PICO Fluid Management Packs consist of 5 individually packaged PICO dressings designed for use with PICO devices.
PICO 7 and PICO 14 are canister-free single use Negative Pressure Wound Therapy Systems and use an absorbent dressing connected to the PICO pump via a tubing and port.

Wound exudate is managed by PICO dressing using a combination of absorption and evaporation. The PICO pump provides the additional benefit of -80mmHg nominal pressure under the dressing, applying Negative Pressure Wound Therapy to the wound.

The subject device is identical to the predicate device (K202157) in terms of it's intended use, operating principles, technological characteristics and design. Clinical information described in next sections demonstrated that the addition to the Indication for Use do not raise different questions of safety or effectiveness.

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

PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System and PICO Fluid Management Packs are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
    - Venous Leg Ulcers – PICO can be used in combination with Graduated Compression Therapy in the management of Venous Leg Ulcers
- Flaps and grafts
- Closed surgical incisions

PICO 7 Single Use Negative Pressure Wound Therapy Systems, PICO 14 Single Use Negative Pressure Wound Therapy Systems and PICO Fluid Management Packs are suitable for use both in hospital and homecare setting.

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

There subject device is identical to the predicate device (K202157) in terms of its intended use, operating principles, technological characteristics and design. The only difference between the subject and predicate device is the addition to Indications for Use to include the use of PICO in combination with Graduated Compression Therapy in the management of Venous Leg Ulcers.

Clinical information described in next sections demonstrated that the addition to the Indication for Use do not raise different questions of safety or effectiveness.

Item	Subject Device	Predicate Device (K202157)	Comparison
Intended Use	For wound management via application of negative pressure to the wound for removal of low to moderate levels of levels of exudate and infectious materials.	For wound management via application of negative pressure to the wound for removal of low to moderate levels of levels of exudate and infectious materials.	Same
Indications for Use	PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System and PICO Fluid Management Packs are indicated for patients who would benefit from a suction	PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System and PICO Fluid Management Packs are indicated for patients who	Addition of "Venous Leg Ulcers – PICO can be used in combination with

	device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include: • Chronic • Acute • Traumatic • Subacute and dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic or pressure) • Venous Leg Ulcers – PICO can be used in combination with Graduated Compression Therapy in the management of Venous Leg Ulcers • Flaps and grafts • Closed surgical incisions PICO 7 Single Use Negative Pressure Wound Therapy Systems, PICO 14 Single Use Negative Pressure Wound Therapy Systems and PICO Fluid Management Packs are suitable for use both in hospital and homecare setting.	would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include: • Chronic • Acute • Traumatic • Subacute and dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic or pressure) • Flaps and grafts • Closed surgical incisions PICO 7 Single Use Negative Pressure Wound Therapy Systems, PICO 14 Single Use Negative Pressure Wound Therapy Systems and PICO Fluid Management Packs are suitable for use both in hospital and homecare setting.	Graduated Compression Therapy in the management of Venous Leg Ulcers" and "When using PICO 7, PICO 14 with another therapy you must comply with indications for both products."

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

Verification and validation activities conducted demonstrate the PICO System continues to perform as intended when used in combination with Graduated Compression Therapy. The principal test methods used to demonstrate performance were simulated wound model tests. Performance data provided in previously cleared 510(k)s for PICO 7, PICO 14, PICO FMP continue to support substantial equivalence and meeting requirements of:

Biocompatibility	**Electrical Safety and EMC**	**Human Factors and Software**	**Wound Model Tests**
ISO 10993-1	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11	IEC 62304, IEC 62366-1	Wound Exudate, Size

21 CFR 807.92 (b)(2): Brief discussion of clinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence

The use of PICO in combination with graduated compression therapy was found to be as safe and effective as predicate device.

Randomized Controlled Study (RCT)

Substantial equivalence is based on a randomized, multi-centre, open-label, controlled trial which investigated PICO in lower extremity ulcers (Kirsner *et al* 2019). A total of 164 patients were available for safety analysis (safety population) and a total of 101 subjects presenting with venous leg ulcers (VLU) and 60 subjects presenting with diabetic foot ulcer were included in the intention-to-treat (ITT) population (n=161 total). Of these patients, 80 received treatment with PICO (intervention). Of the 80 PICO patients, 51 (63.8%) had a VLU. Patients with VLUs were given multilayered compression bandaging. The primary safety endpoint for the study was the occurrence of an adverse event (AE) followed by an evaluation of the extent of exposure to study therapy.

The Kirsner *et al* (2019) study reported that in total, 18 of the subjects using PICO on a VLU (35.3%) identified 40 adverse events (AE). No serious device-related AEs were reported. Nine of the 40 AEs (13.7%) were device related. Of the nine device related AEs, the types of harms identified included maceration, ulcer size increase, blistering and irritation.

A Cochrane Review by O'Meara *et al* (2012) looked at over 40 randomized controlled trials (RCTs) investigating which methods of compression provide the greatest benefit in the management of VLUs. One of the outcomes investigated by the review was the safety profile of compression devices, including the frequency of AEs. As part of the review, an aggregate safety analysis was conducted evaluating the AEs collected from two studies: Franks *et al* (2004) and Iglesias *et al* (2004).

The AE results of the PICO (plus compression) arm from the Kirsner *et al* (2019) study were compared to the aggregate AE frequencies from Franks *et al* (2004) and Iglesias *et al* (2004) studies for compression alone (historical control). A summary of this comparison can be seen in below. As seen in the table below, the frequency of device related AEs associated with the use of PICO with multilayer compression is no higher than that observed with multilayer compression alone (13.7% versus 31.9%, respectively). The types of harms identified from the historical control studies include: maceration, pain, eczema, tissue damage (new ulcer), skin excoriation, skin deterioration, ulcer deterioration, bandaging failure, dryness and the requirement for surgical interventions or hospitalization. As noted above, these harms are similar in the type and severity observed with PICO plus compression.

Percentage frequencies of observed AEs from Kirsner *et al* (2019) and historical control(s).

	Franks *et al* (2004)	**Iglesias *et al* (2004)**	**Franks *et al* (2004) & Iglesias *et al* (2004)**	**Kirsner *et al* (2019) (PICO arm plus compression)**
Percentage of subjects reporting any AE	SSB: 26.2% 4LB: 30.7%	SSB: 53.6% 4LB: 47.2%	SSB: 45.3% 4LB: 42.6%	SSB: N/A 4LB: 35.3%

Percentage of subjects reporting a device related AE	SSB: 10.7% 4LB: 13.3%	SSB: 47.4% 4LB: 39.0%	SSB: 36.2% 4LB: 31.9%	SSB: N/A 4LB: 13.7%
SSB – Short-stretch bandage; 4LB – Four-layer bandage				

It can be concluded from the above findings that PICO used in conjunction with compression therapy does not generate any increased frequency in the number or severity of AEs in patients compared to compression therapy alone.

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

Based on the clinical supporting information provided in this submission, the subject device is substantially equivalent to the legally marketed predicate device (K202157) and there are no different questions of safety or effectiveness.