October 30, 2020

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

Re: K202157
Trade/Device Name: PICO 7 Single Use Negative Pressure Wound Therapy System,
PICO 7Y Single Use Negative Pressure Wound Therapy System,
PICO 14 Single Use Negative Pressure Wound Therapy System,
PICO Fluid Management Pack
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: July 31, 2020
Received: August 3, 2020

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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202157

Device Name
PICO 7 Single Use Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
PICO 7 Single Use Negative Pressure Wound Therapy System is 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)
- Flaps and grafts
- Closed surgical incisions

PICO 7 Single Use Negative Pressure Wound Therapy Systems are suitable for use both in 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202157

Device Name
PICO 7Y Single Use Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
PICO 7Y Single Use Negative Pressure Wound Therapy System is 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)
- Flaps and grafts
- Closed surgical incisions

PICO 7Y Single Use Negative Pressure Wound Therapy Systems are suitable for use both in 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202157

Device Name
PICO 14 Single Use Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
PICO 14 Single Use Negative Pressure Wound Therapy System is 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)
- Flaps and grafts
- Closed surgical incisions

PICO 14 Single Use Negative Pressure Wound Therapy Systems are suitable for use both in 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202157

Device Name
PICO Fluid Management Pack

Indications for Use *(Describe)*

PICO single use negative pressure systems are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as they 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 single use negative pressure systems are suitable for use both in 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY - K202157

PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 7Y Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System, and the PICO Fluid Management Pack.

I. Submitter	
Owner Name/Address:	Smith &Nephew Medical Limited 101 Hessle Road Hull HU3 2BN United Kingdom
Establishment Registration Number:	8043484
Contact Person:	Dr Steeve Lamvohee, Regulatory Affairs Director
Phone Number:	+44 7583 048727
Date Prepared:	08 Sep 2020
II. Device	
Trade Names:	PICO 7 Single Use Negative Pressure Wound Therapy System PICO 7Y Single Use Negative Pressure Wound Therapy System PICO 14 Single Use Negative Pressure Wound Therapy System PICO Fluid Management Pack
Common or Usual Name:	Negative Pressure Wound Therapy powered suction pump
Classification Name:	Powered suction pump (21 CFR 878.4780)
Regulatory Class:	Class II
Product Code:	OMP
510(k) Number:	K202157
III. Predicate Device	
510(k) Number:	K180698
Device name:	PICO 7 Single Use Negative Pressure Wound Therapy System
Clearance Date:	21 August 2018
Recall Information:	The predicate has not been the subject of any recall

IV. Device Description

All of the PICO devices (PICO 7 (K180698), PICO 7Y (K182323), and PICO 14 (K191760) are canister-free single-use Negative Pressure Wound Therapy (NPWT) Systems and use an absorbent dressing connected to a small NPWT pump by a tubing and port. The dressing manages wound exudate by a combination of absorption and evaporation. The pump provides for a -80mmHg nominal pressure under the dressing, applying Negative Pressure Wound Therapy (NPWT) to the wound. PICO Fluid Management Pack are packs of 5 individually packaged PICO Dressings designed for use with PICO devices.

V. Indications for Use

PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 7Y Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System, and the PICO Fluid Management Pack 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)
- Flaps and grafts
- Closed surgical incisions

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

VI. Comparison of Technological Characteristics with the Predicate Device

The technological principle for delivering the negative pressure wound therapy for the subject devices and predicate device are identical. The differences between the subject devices and the predicate device are:
- Updated text for Magnet Warning
- Removal of Pump warning label

Items	Subject Devices: PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 7Y Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System, PICO Fluid Management Pack	Predicate Device: PICO 7 Single Use Negative Pressure Wound Therapy System	Comparison
Indications For Use	PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 7Y Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System, and PICO Fluid Management Pack are indicated for patients who would benefit from a suction device (NPWT) 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, PICO 7Y, PICO 14 Single Use Negative Pressure Wound Therapy Systems and PICO Fluid Management Pack is suitable for use both in a hospital and homecare setting.	PICO 7 Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (NPWT) 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 System is suitable for use both in a hospital and homecare setting.	Same
Environment of use	Hospital, home	Hospital, home	Same

Items	Subject Devices: PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 7Y Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System, PICO Fluid Management Pack	Predicate Device: PICO 7 Single Use Negative Pressure Wound Therapy System	Comparison
Patient Population	Patients who would benefit from a suction device (negative pressure wound therapy)	Patients who would benefit from a suction device (negative pressure wound therapy)	Same
Materials	PU Plastic pump casing	PU Plastic pump casing	Same
Single-use or Reusable	Single use	Single use	Same
Method of Sterilization	Pump, dressing and fixation strips sterilized by ethylene oxide	Pump, dressing and fixation strips sterilized by ethylene oxide	Same
Biocompatibility	Dressing complies with ISO 10993	Dressing complies with ISO 10993	Same
Type of Pump	Custom designed “voice-coil” pump controlled by microprocessor	Custom designed “voice-coil” pump controlled by microprocessor	Same
Electrical Safety Testing	Complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11	Complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11	Same
Instructions for Use	Addition of the word medical • If you have an electronic medical device and are helping take care of somebody else using the PICO 7 system.	• If you have an electronic device and are helping take care of somebody else using the PICO 7 system	Magnet warning box in HCP and Patient IFU changed
	As requested by the FDA, addition of “MR Unsafe. You must remove the PICO 7 pump from the dressing before entering the MRI suite. Do not bring PICO 7 into the MRI scan room. The device presents a projectile hazard.”	N/A	Addition of warning to HCP and Patient IFU
	Texts amended in “Important Information Section” and “Glossary of Symbols”	The PICO [#] pumps contain a MAGNET. Keep the PICO [#]	Important Information and Glossary of

Items	Subject Devices: PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 7Y Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System, PICO Fluid Management Pack	Predicate Device: PICO 7 Single Use Negative Pressure Wound Therapy System	Comparison
	The PICO [#] pumps contain a MAGNET. Keep the PICO [#] pumps at least 4 inches (10 cm) away from other medical devices at all times. As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices.	pumps at least 4 inches (10 cm) away from other medical devices at all times. Failure to do so can cause the other medical device to fail which can result in serious harm including death.	Symbols in HCP and Patient IFU changed. Texts removed "Failure to do so can cause the other medical device to fail which can result in serious harm including death." Texts added "As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices."
Warning Label on front of Pump	No warning label on the front of the pump.		Warning Label Removed

VII. Performance Data

Performance data provided in previously cleared 510(k)s for PICO 7, PICO 7Y and PICO 14 Single Use Negative Pressure Wound Therapy Systems (including PICO Fluid Management Pack) continue to support substantial equivalence. Additional data is provided to support the proposed change including testing of magnetic field, an analysis of postmarket surveillance, and a risk

analysis. In the cleared 510(k)s for PICO 7, PICO 7Y and PICO 14 Single Use Negative Pressure Wound Therapy Systems (including PICO Fluid Management Pack), the device met requirements for:

Biocompatibility:

- 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.

Testing included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Pyrogen Testing

Electrical Safety and Electromagnetic Compatibility:

- IEC 60601-1
- IEC 60601-1-11
- IEC 60601-1-6
- IEC 60601-1-2

Wound model testing:

- Wound exudate
- Wound size
- NPWT Wound flow rate
- Testing duration
- Pressure sampling rates

Magnetic Field Testing:

Bench testing demonstrated that the average magnetic field strength of PICO Family pump is weaker than multiple everyday devices (e.g. laptops, phones, tablets, and headphones). These products are abundant in today's society and do not pose an unacceptable risk to patients with implantable medical devices (IMDs). The PICO pump does not significantly change the magnetic environment an IMD user may encounter.

Post Market and Risk Analysis:

A systematic literature review was conducted of IMDs and magnetic interference and this demonstrated that although the risk of magnetic interference with implantable medical devices exists, the risk is not as high as had been originally assessed. Magnetic fields are present in the everyday environment which are comparable with those presented by the PICO devices, however, there are no risks that have been reported in the clinical literature that relate to actual death or serious harm. A comprehensive review of over 60,000 records from the MAUDE database as well as the Smith +Nephew PICO devices complaint data confirmed the literature review outcome.

VIII. Conclusion

Data to confirm substantial equivalence to the predicate were provided in the FDA cleared 510(k) for PICO Family of Single Use Negative Pressure Wound Therapy Systems. The proposed labeling changes are supported by updated IFUs, evaluation of risk and updated risk analysis, and magnetic strength testing. The subject devices are substantially equivalent to the predicate device.