February 2, 2018

Smith & Nephew Medical Limited
Susan McLoughlin
Regulatory Affairs Director, Advanced Wound Management
101 Hessle Road
Hull, hu3 2bn GB

Re: K172005
Trade/Device Name: PICO 7 Single Use Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: December 21, 2017
Received: December 26, 2017

Dear Susan McLoughlin:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172005

Device Name
PICO 7 Single Use Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
PICO 7 is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it may promote would 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.

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

PICO 7 Single Use Negative Pressure Wound Therapy System

General Information

Submitter Name/Address:	Smith & Nephew Medical Limited 101 Hessle Road, Hull HU3 2BN United Kingdom
Establishment Registration Number:	8043484
Contact Person:	Susan McLoughlin, Regulatory Affairs Director
Phone Number	+44 1482 673637
Date Prepared:	1 February 2018

Device Description

Trade Name:	PICO 7 Single Use Negative Pressure Wound Therapy System
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

Predicate Device Information

510(k) Number:	K163387
Device:	PICO Single Use Negative Pressure Wound Therapy System
Clearance Date:	April 18, 2017

Device Description

PICO 7 Single Use Negative Pressure Wound Therapy System is a small, lightweight, portable, magnet containing electro-mechanical pump system connected through a flexible tube to a super-absorbent, gentle adhesive dressing. Secondary fixation strips are also provided to ensure an adequate seal is achieved. The pump, the dressing and fixation strips are supplied sterile and for single use. PICO 7 was designed to deliver negative pressure wound therapy to low and to moderate exudate levels of acute and chronic wound types. PICO 7 Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting. A carry bag is not provided with the system however will be available to order separately.

Indications for Use

PICO 7 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 Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

Comparison between New and Predicate Devices

The Indications for Use statement of the PICO 7 Single Use Negative Pressure Wound Therapy System is identical to the predicate device. The technological principal for delivering the negative pressure wound therapy for both the subject and predicate devices are identical. The main differences between the subject device and the predicate device are:

(a) the introduction of a new pump to deliver negative pressure,

(b) introduction of a magnet to the device,

(c) the introduction of dual dressing kits and single dressings kit labelled as PICO 7 Single Use NPWT System,

(d) the introduction (addition to existing range) of PICO Fluid Management Pack with 5 individually packaged dressings for use with PICO Single Use Negative Pressure Wound Therapy systems,

(e) the extension of wear time of the dressings when used on moderately exuding wounds.

Non-Clinical Tests (Bench)

The following bench tests have successfully been completed:

- Wound Model Testing of PICO 7 Kits – 10x20cm, 25x25cm, small multisite 15x20cm, large multisite 20x25cm dressings at low and moderate flow rate

The results of the tests showed that all of the dressings managed fluid at a flow rate modelling a low (0.6 g/cm^2/24 hours) and a moderately exuding wound (1.1 g/cm^2/24 hours) respectively for a simulated wound of 25% of the dressing absorbent pad area. The results also showed that the dressings maintained negative pressure within the test requirements of -60 mmHg to -100 mmHg for a minimum of 95% of the test time at the simulated wound base throughout the test. Based on the results of the tests it can be concluded that the PICO 7 systems can be used for their intended purposes.

- Wound Model Testing of PICO 7 kits – 10x20cm and 25x25cm dressings at low and moderate flow rate (vertical orientation)

The results of the tests showed that all of the dressings managed fluid at a flow rate modelling a low (0.6 g/cm^2/24 hours) and a moderately exuding wound (1.1 g/cm^2/24 hours) respectively for a simulated wound of 25% of the dressing area. The results also showed that the dressings maintained negative pressure within the test requirements of -60 mmHg to -100 mmHg for a minimum of 95% of the test time at the simulated wound base throughout the test. Based on the results of the tests it can be concluded that the PICO 7 systems can be used for their intended purposes.

Human Factors

PICO 7 has been evaluated according to FDA guidance 'Applying Human Factors and Usability Engineering to Medical devices, Feb 3rd 2016' and IEC62366-1:2015. Critical tasks were identified following a risk management process and a series of preliminary testing carried out with the two identified user groups, Healthcare Professionals and Lay Users, in order to optimize the design. Following this a summative study was carried out on the entire device followed by an additional study to assess labelling improvements. The studies concluded that the device labelling is safe and effective for its intended users in the intended environments of use.

Biocompatibility and Sterilization Testing

PICO 7 Single Use Negative Pressure Wound Therapy System has been evaluated according to the Biological Evaluation of Medical Devices Standard BS EN ISO 10993, with particular reference to Part 1 (2009): Evaluation and testing within a risk management process and FDA guidance 'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". PICO 7 Single Use NPWT Use System uses the same dressings with soft port as PICO Single Use NPWT System. The biocompatibility of the dressings with soft port used in PICO Single Use NPWT System has been addressed and cleared in 510(k) K166387,

April 18, 2017. The exterior pump components have been assessed through chemical characterisation testing, review of compliance to recognised standards, ethylene oxide and ethylene chlorohydrin residuals testing and supplier biocompatibility test statements.

Electrical Safety and Electromagnetic Compatibility (EMC)

PICO 7 Single Use Negative Pressure Wound Therapy System has been tested and assessed respectively in accordance with the following electrical safety standards and has been found to be in compliance with the following standards IEC60601-1, IEC60601-1-2, IEC60601-1-6 and IEC60601-1-11.

Conclusions

In establishing substantial equivalence to the predicate devices, Smith & Nephew Medical Ltd evaluated the indications for use, materials, technology, product specifications and energy requirements of the device. Performance testing, service life testing and electrical safety testing has been completed to demonstrate that the PICO 7 Single Use Negative Pressure Wound Therapy System is substantially equivalent to the predicate for the intended use.