August 21, 2018

Smith & Nephew Medical Limited
% Kulsum Master
Director Regulatory Affairs, US Region
Smith & Nephew
7000 West William Cannon Drive
Austin, Texas 78735

Re: K180698
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: May 10, 2018
Received: May 14, 2018

Dear Kulsum Master:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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)*
K180698

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 (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.

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.

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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
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United Kingdom

Establishment Registration Number: 8043484

Contact Person: Lavinia Tompkins, Senior Regulatory Affairs Specialist

Phone Number +44 1482 225181

Date Prepared: July 16, 2018

Application Correspondent: Smith & Nephew Inc.
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Austin,
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USA

Contact Person: Kulsum Master, Director Regulatory Affairs, US Region

Phone Number: +1 512-358-5720

Device Description

510(k) Number:	K180698
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

	Primary Predicate Device	**Secondary Predicate Device**
510(k) Number:	K172005	K151436
Device:	PICO 7 Single Use Negative Pressure Wound Therapy System	PICO Single Use Negative Pressure Wound Therapy System
Clearance Date:	February 02, 2018	January 28, 2016

Device Description

PICO 7 Single Use Negative Pressure Wound Therapy System is a small, lightweight, portable, 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.

Indications for Use

PICO 7 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 in both a hospital and homecare setting.

Comparison between New and Primary Predicate Device

The Indications for Use statement of the PICO 7 Single Use Negative Pressure Wound Therapy System is identical to that of the primary and secondary predicate devices. 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 primary predicate device are:

1) Introduction of a check valve (1-way valve) into the PICO 7 device to isolate the internal air leak caused by the normal operation of the pump mechanism from the pressure sensor.
2) To enable the addition of the check valve (1-way valve), the manifold within the device casing required resizing.
3) Minor software amendments which have been submitted as part of this 510(k) application. The amendments do not affect the performance, function, or indicators of the device.
4) Extension of shelf life of PICO 7 system from 6 to 18 months.

The following testing has been completed on the subject device:

Non-Clinical Tests (Bench)

Wound Model Testing

Wound model testing was conducted on PICO 7 Kits (10x20cm and 25x25cm dressings) at low and moderate flow rate in vertical and horizontal positions.
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.

Visual Indicator Performance Testing

- Dressing Full Indicator

  Testing was conducted on the PICO 7 system using water and simulated wound fluid to simulate a worst case scenario where the dressing reaches

maximum capacity and the filter in the dressing becomes blocked with fluid.

All test results showed when the dressings reached their maximum capacity the subject device was able to detect blockages and activate the “dressing full” indicator no later than 2 hours after the occlusion had occurred.

Based on the test results, it can be concluded that the PICO 7 devices can be used for their intended purposes.

- Air Leak Indicator

  Air leak testing was conducted on PICO 7 by introducing deliberate air leaks into the system to show that when the system has a high leak rate, the leak indicators activate to alert the user to inspect the dressing application and address the point of air ingress/ air leak.

  Test results showed that air leak indicator was activated at specified time points in line with the test requirements representing the initial application of the system to achieve the therapeutic negative pressure range of -60mmHg to -100mmHg (target -80mmHg); and maintenance of the therapeutic pressure range.

  Based on the test results, it can be concluded that the PICO 7 devices can be used for their intended purposes.

- Low Battery Indicator

  Low battery indicator testing of the PICO 7 system at pre-defined time periods which allow users to respond to the battery state.

  The device was operated until the “battery low” indicator was activated, once activated, the device was continued to be operated for a minimum of a further 12 hours to ensure that the device reached “critical battery low” state.

All test results showed that the “battery low” indicator activated and flashed for a minimum of 12 hours prior to the device entering “critical low battery” state and that once the device had entered the “critical low battery” state, pressing the play/pause button of the device enabled the “battery low” indicator to flash 3 times.

Based on the test results, it can be concluded that the PICO 7 devices can be used for their intended purposes.

Acoustic Testing

Acoustic testing was conducted to demonstrate that the level of noise emitted from the subject device whilst addressing the internal air leak caused by the normal operation of the pump mechanism remained acceptable as defined within ANSI/AAMI HE75:2009/(R)/2013 in line with the recommendation for frequent peaks at night in a convalescent area.

Test results showed that during the normal operation of the pump mechanism, the subject device emitted an average noise level of 27.6dB and that the maximum noise emitted by the device (LAF_{max}) did not exceed 35dB in accordance with ANSI/AAMI HE75:2009/(R)/2013.

Based on the test results, it can be concluded that the PICO 7 devices can be used for their intended purposes.

Electromagnetic Compatibility and Electrical Safety Testing

PICO 7 Single Use Negative Pressure Wound Therapy System has been tested and assessed respectively and has been found to be in compliance with the following standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012 – C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment -

Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)

- IEC 60601-1-2 Edition 4.0 2014-02 – Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- IEC 60601-1-6 Edition 3.1 2016-10 – Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- IEC 60601-1-11 Edition 2.0 2015-01 – Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
- IEC 62366 – Medical Devices – Application of Usability Engineering to Medical Devices

Shelf Life

The PICO 7 system has been evaluated using real time and accelerating ageing challenge conditions and a combination of simulated wound model testing as well as specification testing to demonstrate system functionality over the duration of the shelf life.

Test results showed that all 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. Furthermore, all specification test results complied with the acceptance criteria as defined within the test requirements. The results of all tests showed that the subject device was able to maintain its functionality over the duration of the ageing study and that a

shelf life of 18 months can be applied to the PICO 7 system. Therefore, it can be concluded that the PICO 7 systems can be used for their intended purposes.

Conclusions

In establishing substantial equivalence to the predicate device, 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 primary and secondary predicate devices for the intended use.