January 18, 2019

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

Re: K182323
Trade/Device Name: PICO 7Y 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 19, 2018
Received: December 20, 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,

Kimberly Ferlin -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182323

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

Indications for Use *(Describe)*

PICO 7Y 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 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.

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510(K) SUMMARY
K182323

PICO 7Y 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:	Shruthi Bhat, Regulatory Affairs Specialist
Phone Number	+1 512-895-1295
Date Prepared:	August 24, 2018
Application Correspondent:	Smith & Nephew Inc. 7000 West William Cannon Drive, Austin, Texas, 78735, USA
Contact Person:	Kulsum Master, Director Regulatory Affairs, US Region
Phone Number:	+1 512-358-5720

Device Description

Trade Name:	PICO 7Y 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:	K180698
Device:	PICO 7 Single Use Negative Pressure Wound Therapy System
Clearance Date:	August 21, 2018

Device Description

PICO 7Y Single Use Negative Pressure Wound Therapy System is a small, lightweight, portable, electro-mechanical pump system connected through a Y-shaped tube known as the "Y-Connector" to two super-absorbent, gentle adhesive dressings. Secondary fixation strips are also provided to ensure an adequate seal is achieved. The pump, the dressings and fixation strips are supplied sterile and for single use. PICO 7Y was designed to deliver negative pressure wound therapy to low and moderate exudate levels of acute and chronic wound types. PICO 7Y Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

Indications for Use

PICO 7Y 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 Systems are suitable for use both in a hospital and homecare setting.

Comparison between subject device and predicate device

The main differences between the cleared PICO 7 System (K180698) and the subject device are as follows:

1. Introduction of a Y connector to the existing PICO 7 pump device (K180698) allowing delivery of negative pressure to two wounds simultaneously. The O-ring component within the pump device has been changed to enable securing the Y Connector within the pump device casing.
2. Extension of the soft port connected to the large multisite dressing kit for use with PICO 7Y Single Use Negative Pressure Wound Therapy System. The dressing components are identical to existing large multisite dressings (20 x 25cm or 7.9 x 9.8 inches); however the soft port has been extended for user convenience so that when using the device on two wounds, use of the extension tubing is not necessary.
3. Introduction of a new packaging configuration incorporating dimensional changes to accommodate for additional PVC tubing, the instructions for use being presented as booklets, and the “book” style carton used in the predicate device being replaced with a tuck end carton.
4. Replacement of the ‘Dressing Full’ indicator with the ‘Check Dressing’ indicator to remind the user to check their dressing every 24hours.

5. Corresponding changes to the software to accommodate the use of the system on two wounds and replacement of the ‘Dressing Full’ indicator with ‘Check Dressing’ indicator.
6. Replacement of Alkaline batteries with Lithium batteries which are identical to those which were used in a previously cleared version of PICO Single Use Negative Pressure Wound Therapy System (K163387).
7. Corresponding changes to the instructions for use to reflect the design changes made to the subject device.

The following testing has been completed on the subject device:

Non-Clinical Tests (Bench)

- Wound model testing was conducted on the PICO 7Y system and compatible dressings from the PICO range (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 7Y device and accessories can be used for their intended purposes.

- Wound model testing was conducted on the PICO 7Y dressings in the absence of negative pressure in vertical and horizontal positions. The results of the tests showed that all of the dressings in a vertical position managed fluid at a flow rate modelling moderate and low exuding wounds

with no NPWT (0.5 g/cm^2/24hrs and 0.3g/cm^2/24hrs) for a simulated wound of 25% of the dressing absorbent pad area. Based on the results it can be concluded that the PICO 7Y dressings (large multisite) can handle fluid without the presence of negative pressure.

- Functionality testing was conducted on the PICO 7Y device to demonstrate that PICO 7Y pump unit has been adequately designed to handle small (minimum total 50ml volume) and large (maximum total 600ml volume) simulated wounds simultaneously. The results of the tests (using one canister of 50ml and two 300ml canisters respectively to simulate small and large wounds) showed that the pump pressure limits were recorded between -100 to -60mmHg and had a cycle of ≥10mmHg and the time taken to reach the target negative pressure was less than 100seconds. This demonstrated the pump can be used for its intended purpose.

- The ability of the PICO 7Y device to deliver negative pressure whilst in a battery low state was assessed. Test results showed that the PICO 7Y device can continue to deliver negative pressure when the device is in a battery low state demonstrating that the pump can be used for its intended purpose.

- Check dressing indicator performance testing was conducted on the PICO 7Y device. The results of the tests showed that the check dressing indicator successfully activated after 24 hours use, while maintaining negative pressure.
  After resetting, per the Instructions for Use and Intended Use, the second occurrence of the check dressing indicator activated after a minimum of 23 hours and 45 minutes and a maximum of 24 hours and 10minutes. Based on the test results, it can be concluded that the PICO 7Y devices can be used for their intended purposes.

- Performance testing was conducted on the PICO 7Y device to demonstrate that the dressing is able to manage exudate in a scenario when NPWT is lost after the port becomes blocked, thus mitigating risk of maceration. Test results show that the system when tested under the maximum clinically acceptable flow rate successfully manages exudate during the delivery of negative pressure and following the loss of negative pressure until the 7 day service life has been achieved. As such the design of the dressing provides for inherent safety and acts as an effective primary mitigation for the risk that a dressing is left in place after a port blockage scenario has occurred.

- Performance bench testing was conducted to confirm system performance and demonstrate that when one dressing soft port is blocked, pressure is maintained within the specified range on the non-blocked dressing. The results demonstrate that when one dressing soft port is blocked due to oversaturation of the dressing, the PICO 7Y device is still able to deliver acceptable levels of negative pressure to the non-blocked dressing.

- Air leak testing was conducted on PICO 7Y device 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 7Y devices can be used for their intended purposes.

Electromagnetic Compatibility and Electrical Safety Testing

PICO 7Y 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 7Y 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 without any pressure readings being lower than -235mmHg. 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 24 months (2 years) can be applied to the PICO 7Y system. Therefore, it can be concluded that the PICO 7Y device and accessories can be used for their intended purposes.

Human Factors/Usability Engineering Testing

A summative study was carried out in the US. Instructions for Use (IFU) validations were also carried out to demonstrate that the intended users (Lay Users, Healthcare Professionals) can follow the instructions as intended and understand information for safety from the instructions for use.

The summative study activities did not result in any patterns of use errors that when assessed resulted in an unacceptable residual risk. PICO 7Y system has appropriate design mitigations in order to prevent and control harm occurring due to use error. It was therefore concluded that PICO 7Y system is safe and effective for use by the intended users, for the described uses in the expected environments.

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 7Y Single Use Negative Pressure Wound Therapy System is substantially equivalent to predicate device for the intended use.