April 6, 2018

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

Re: K180614
Trade/Device Name: PICO 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: March 6, 2018
Received: March 8, 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. 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,

Jennifer R. Stevenson -S3

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)*
K180614

Device Name
PICO Single Use Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
PICO 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 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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K180614

510(K) SUMMARY

PICO 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:	Lavinia Tompkins, Senior Regulatory Affairs Specialist
Phone Number	+44 1482 225181
Date Prepared:	March 06, 2018

Application Correspondent:	Smith & Nephew Inc. 7000 West William Cannon Drive, Austin, Texas, 78735, USA
Contact Person:	Kulsum Master, Director Regulatory Affairs
Phone Number:	1-512-358-5720

Device Description

Trade Name:	PICO 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:	K172521
Device:	PICO Single Use Negative Pressure Wound Therapy System
Clearance Date:	September 20, 2017

Device Description

PICO 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 was designed to deliver negative pressure wound therapy to low and to moderate exudate levels of acute and chronic wound types. PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting.

Indications for Use

PICO 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 Device

The Indications for Use statement of the PICO Single Use Negative Pressure Wound Therapy System is identical to the predicate device. The subject device and the predicate device are the same. The only differences between the subject device and the predicate device are the alternative, equivalent, non-critical components introduced to the printed circuit board assembly to resolve future resourcing issues.

The subject device incorporating the alternative, non-critical components has been tested against for functionality in accordance 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

Testing demonstrated that the alternative, non-critical components perform equivalently to the current, non-critical components and do not impact device performance. The pumps were able to operate within a pressure range of -60mmHg to -100mmHg (-80mmHg nominal) and remained compliant with IEC requirements as listed above.

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. As there are no design differences between the subject device and the predicate device, PICO Single Use Negative Pressure Wound Therapy System is substantially equivalent to the predicate for its intended use.