September 15, 2017

Smith & Nephew Medical Limited
Samantha Neilson
Senior Regulatory Affairs Manager, Advanced Wound Management
101 Hessle Road
Hull, HU3 2BN GB

Re: K172519
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: August 18, 2017
Received: August 21, 2017

Dear Samantha Neilson:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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
Indications for Use

510(k) Number (if known)
K172519

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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SECTION 7: 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: Samantha Neilson, Senior Regulatory Affairs Manager
Phone Number +44 1482 673790
Date Prepared: August 18, 2017

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: K163387
Device: PICO Single Use Negative Pressure Wound Therapy System
Clearance Date: April 18, 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 difference between the subject device and the predicate device is the compliance against the requirements of IEC60601.

The subject device has been retested to demonstrate compliance with


while the predicate device was tested and cleared to the requirements of

- IEC 60601-1-11: 2010 (First Edition) 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

The Instructions for Use and the pump label been updated to reflect a change in test house. The cleared device was tested and certified by CSA Group (Canada)
whilst the subject device was tested and certified by Intertek Testing Service NA, Inc (USA).

**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. 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 the intended use.