December 5, 2019

Smith & Nephew Medical Limited
Sam Greenhalgh
Senior Regulatory Affairs Specialist
101 Hessle Road
Hull, HU3 2BN Gb

Re: K191760
Trade/Device Name: PICO 14 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: November 1, 2019
Received: November 4, 2019

Dear Sam Greenhalgh:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 M. Ferlin, Ph.D.
Assistant Director (acting)
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*

K191760

Device Name
PICO 14 Single Use Negative Pressure Wound Therapy System

Indications for Use *(Describe)*

PICO 14 is indicated for patients who would benefit from a suction device (NPWT) 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 14 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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K191760

510(K) SUMMARY

PICO 14 Single Use Negative Pressure Wound Therapy System

General Information	
Owner Name/Address:	Smith & Nephew Medical Limited 101 Hessle Road, Hull HU3 2BN United Kingdom
Establishment Registration Number:	8043484
Contact Person:	Sam Greenhalgh, Senior Regulatory Affairs Specialist
Phone Number	+44 1482 673436
Date Prepared:	December 4th, 2019
Device Description	
Trade Name:	PICO 14 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)
Medical Device Class:	Class II
Product Code:	OMP
Predicate Device Information	
510(k) Number:	K180698
Device name:	PICO 7 Single Use Negative Pressure Wound Therapy System
Clearance Date:	August 21, 2018

Device Description

PICO 14 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.

Description of the Patient Population for which the device is intended:

The target patient population for which the device is intended is unchanged between the subject device (PICO 14) and the predicate device (PICO 7). The patient population is: Patients who would benefit from a suction device (negative pressure wound therapy).

Indications for Use

PICO 14 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 14 Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.

Comparison of Subject and Predicate Devices

Comparison Between PICO 7 (Predicate Device) and PICO 14 (Subject Device)	
Software	The only changes to the software are minor convenience updates to the maximum pump down times and to allow for use over a 14 day period instead of 7 days (predicate device). There are no changes to the function of the system with respect to the delivery of NPWT,
Packaging format	The packaging format been modified to provide a more simple manufacturing process. The materials used in the packaging are unchanged however the IFU will now be in an A4 book format and the carton will be a single box with an insert rather than the book format.
Indications for Use statement	PICO 7 and PICO 14 are identical.
Instructions for use	The Instructions for Use are largely the same as the predicate system. The main changes are to provide clarity with respect to wound depth. The updated wording is clear that PICO 14 is suitable for use on wounds up to 4.5cm deep. Wounds greater than 0.5cm (1/4 in.) in depth are likely to require a foam or gauze negative pressure wound therapy filler to ensure adequate treatment of all the wound surface. Wounds treated with the PICO 14 system should generally be no more than 4.5cm (1 ¾ in.) in depth and must not contain exposed arteries, veins, nerves or organs.
Technological principal for delivering the negative pressure wound therapy	PICO 7 and PICO 14 are identical
PICO Pump	Embossing and symbol changes to change from 7 day use to 14 day use and change to icon bar color (from gray to black).
Physical components of the pumps, dressings and tubing	PICO 7 and PICO 14 are identical

Batteries	While an additional set of batteries are now provided, The predicate system could require a battery change, which was already communicated to the user. Two sets of batteries will be provided in the case that the user needs to change the batteries (the predicate device provides one set of batteries). One of the battery sets will be provided sterile within the primary pump tray packaging (identical to the predicate device) and one set is provided non-sterile as an extra set.
System-use time	The system use time has changed from 7 days (predicate device) to 14 days (subject device).
User interface	PICO 14 remains similar, with only minor changes to the product appearance and packaging
Electrical Safety and Electromagnetic Compatibility (EMC)	PICO 7 and PICO 14 are identical

These minor changes discussed above are not considered to change the safety profile of the system, nor do they raise any new questions of safety or efficacy.

The changes do not reflect any new user tasks, nor do they impact any of the critical tasks associated with the use of PICO and the users are not expected to complete any new tasks.

Given the identical nature of the physical aspects of the predicate system and PICO 14, much of the data to support the product is the same as the predicate data.

Non-Clinical Tests (Bench)

The PICO 14 Single Use Negative Pressure Wound Therapy System delivers the same nominal negative pressure of -80mmHg and the same pressure profile as the PICO 7 System. The only functional changes are to increase the use time from 7 to 14 days, two repetitions of the dynamic duty cycle used in PICO 7 to maximize power use of 14 days instead of 7 days and changes to the maximum Initial Pump Down (IPD) and Maintenance Pump Down (MPD) times.

Since the system continues to act exactly as with the PICO 7 system, the bench testing provided is to demonstrate two aspects:

1) The system can function for 14 days without failure
2) The system continues to function when used on wounds up to 4.5cm deep

14 Day System Use

Bench tests have successfully been completed and represent worst case scenarios. The wound model tests demonstrate that, in a clinically representative scenario, the PICO 14 system can manage wound exudate and deliver Negative Pressure over 14 days.

Deep Wound Model Testing

Bench tests have successfully been completed and represent worst case scenarios. The wound model tests demonstrate that, in a clinically representative scenario, the PICO 14 system can manage wounds up to 4.5cm deep.

The testing utilized PICO pumps from the predicate submission; as discussed throughout this 510(k), the NPWT delivery profile is unchanged between the subject and predicate devices, hence the data from the predicate system as applicable to the subject system.

Clinical Evidence Summary

Clinical evidence was provided to support the use of PICO 14 in wounds with depths up to 4.5 cm. The study population included all patients at two community care access centers, who were admitted and received care for a chronic wound (pressure ulcer (PU), diabetic foot ulcer (DFU), venous leg ulcer (VLU), surgical ulcer (open incision)) from March 31, 2016 until March 31, 2018. 3,159 patients were followed from admission to healing. 917 patients used the PICO device and 409 of those patients had wound depths greater than 2 cm in which 233 were DFUs, 18 were PUs, 147 were dehisced surgical wounds, and 11 were VLUs. Time

to healing, number and duration of dressing changes, and adverse events were recorded.

The adverse event rate in the PICO groups (depth < 2cm 1.2% and depth >2cm 2.5%) was lower than the non-PICO group (6.6%). There were no PICO device related adverse events in the > 2cm group. Data were provided on the 32 of the 917 (2.8%) patients that discontinued PICO. 11 of those patients discontinued due to infection (1) or drainage (10) and for the drainage, the clinician decided the exudate rate had increased beyond the indicated low to moderate exudate rate. The data provided demonstrates safety of the device for wounds with depths up to 4.5 cm.

Biocompatibility, Sterilization and Electrical Testing

PICO 14 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 14 Single Use NPWT Use System uses the same dressings with soft port as the predicate PICO Single Use NPWT System; the materials are identical and therefore no new biocompatibility data are required. Additionally, the exterior pump components remain identical to the predicate device already cleared by the FDA.

The PICO 14 Single Use Negative Pressure Wound Therapy System has the same electrical characteristics as the predicate system (K180698), with the only changes being a software update. The software changes will not impact on the electrical safety of the system.

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. It was confirmed that the PICO 14 Single Use Negative Pressure Wound Therapy System continues to use the same materials as the predicate system and provides the same user interface.

Performance testing has been completed to demonstrate that the PICO 14 Single Use Negative Pressure Wound Therapy System is substantially equivalent to the predicate for the intended use.