DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 28, 2016

Smith & Nephew Medical Ltd
% Samantha Neilson
Regulatory Affairs Manager
Smith & Nephew, Inc.
970 Lake Carillon Drive Suite 110
St Petersburg, Florida 33716

Re: K151436
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: May 27, 2015
Received: May 28, 2015

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 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 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 yours,

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)*
K151436

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 in both 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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510(K) SUMMARY

PICO Single Use Negative Pressure Wound Therapy System

General Information

Submitter Name/Address:	Smith & Nephew Medical Inc 970 Carillon Drive, Suite 110 Saint Petersburg, Florida, 33716
Establishment Registration Number:	3006760724
Contact Person:	Terry McMahon, Director Regulatory Affairs & Quality, North America
Phone Number	+727 399 3468
Date Prepared:	May 27, 2015

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:	K112127
Device:	PICO Single Use Negative Pressure Wound Therapy System
Clearance Date:	May 16, 2012

Device Description

PICO Single Use Negative Pressure Wound Therapy System is a small, lightweight, portable suction device consisting of an electric motor driven, twin-diaphragm, vacuum pump connected to a super-absorbent, gentle adhesive dressing. The pump, dressing and secondary fixations strips are supplied sterile and single use. The dressing is applied to the wound and secondary fixation strips are placed over the outside edges to help hold the dressing in place. When the suction pump is turned on, air is pulled out of the dressing creating negative pressure and drawing excess fluid from the wound into the dressing. The pump is battery operated and is supplied with two AA lithium batteries which provide up to 168 hours (7 days) of battery life depending upon leak rate. The batteries can be replaced if required. The pump is programmed to stop working after 168 hours (7 days) of use and will not re-start after this time, even with new batteries. Negative pressure will not be applied at this point. PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and homecare setting. A carry bag is not provided with the system however will be available to order separately.

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 Devices

The Indications for Use statement of the PICO Single Use Negative Pressure Wound Therapy System is identical to the predicate devices. The technological principal for delivering the negative pressure wound therapy for both the subject and predicate devices are identical. Modifications to the cleared device include:

(a) Changes to the pump unit as follows: integration of reverse polarity protection into battery cover, modification of battery cover, removal of pump weights, change in acoustic dampening foam, modification of inlet connector, addition of travel limiters, modification of pump cases, change to transistor
(b) Increase in the length of tube connecting the dressing to the pump
(c) Increase in shelf life
(d) Changes to instructions for use to comply with 3rd Edition of IEC 60601
(e) Software change
(f) Inclusion of microfuse

Non-Clinical Tests (Bench)

The following bench tests have successfully been completed:

- PICO 1.5 Micofuse Characterization Test Report

The results of the tests showed that the temperature was within the allowable tolerance limits as per the requirements of IEC 60601-1 and also showed that the fuses did not break and the soldering was intact after the drop tests. All the tests met the acceptance criteria. Therefore it was concluded that the microfuse was fit for purpose.

- PICO 1.6 Microfuse Accelerated Life Test Summary Report

The results showed that the current consumption attributed to the fuses was comparable over the accelerate life. It was concluded the effect of the microfuse on the overall power

consumption of the device will be unchanged over the shelf-life of the device and will therefore not cause unacceptable power draw which would limit the life of the device below the nominal service life. All fuse interventions occurred well within the nominal fuse failure time (0.21 seconds) at all time points. The fuse intervention can therefore be expected to occur as designed throughout a 3 year shelf life of the device. Based on the above, the tests have been considered a PASS and meet the set acceptance criteria.

- PICO 1.6 Microfuse Service Life Characterisation Report (12 ml/min nominal leak)

At the end of execution of the FULL TEST suite, the following results were observed (a) No batteries replacement was required over the seven days of Service Life; (b) The End of Life countdown timer was not reached before 7 days of operation; (c) All the microfuse were still assembled and in function after the seven days of Service Life; and (d) No pump leak was observed during while the pump was operational. Based on the above, it was concluded that the functionality of the pump, over the service life of PICO system, is unaffected by the addition of the microfuse.

- PICO 1.6 Wound Model Testing of PICO pumps with microfuse – 25 x 25 cm dressing at moderate flow rate over 3 days

The results of the tests showed that all of the dressings managed fluid at a flow rate modelling a moderately exuding wound (1.1 g/cm^2/24 hours) 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 inclusion of the microfuse in PICO pumps did not affect the performance of the PICO System over a simulated use period of 3 days.

- PICO 1.6 Wound Model Testing of PICO pumps with microfuse – 10 x 20 cm dressing at moderate flow rate over 3 days

The results of the tests showed that all of the dressings managed fluid at a flow rate modelling a moderately exuding wound (1.1 g/cm^2/24 hours) 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 inclusion of the microfuse in PICO pumps did not affect the performance of the PICO System over a simulated use period of 3 days.

- PICO 1.6 Wound Model Testing of PICO pumps with microfuse – 25 x 25 cm dressing at low flow rate over 4 days

The results of the tests showed that all of the dressings managed fluid at a flow rate modelling a moderately exuding wound (0.6 g/cm^2/24 hours) for a simulated wound of 25% of the dressing 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 inclusion of the microfuse in PICO pumps did not affect the performance of the PICO System over a simulated use period of 4 days.

- PICO 1.6 Wound Model Testing of PICO pumps with microfuse – 10 x 20 cm dressing at low flow rate over 4 days

The results of the tests showed that all of the dressings managed fluid at a flow rate modelling a moderately exuding wound (0.6 g/cm^2/24 hours) for a simulated wound of 25% of the dressing 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 inclusion of the microfuse in PICO pumps did not affect the performance of the PICO System over simulated use period of 4 days.

Biocompatibility and Sterilization Testing

There were no modifications to the patient contacting components or materials of the predicate device K112127 where additional safety tests were required to meet the requirements of ISO 10993-1. Therefore the results of the previous tests mentioned below are still valid and can be used to show that the PICO Single Use Negative Pressure Wound Therapy System is still safe for its intended use. In the previous cleared 510(k), K112127, the biocompatibility of PICO Single Use Negative Pressure Wound Therapy System has been demonstrated through assessment according to ISO 10993-1 Biological Evaluation of Medical Devices, and appropriate tests had been conducted using final product that has been packaged and sterilised. These tests included cytotoxicity, sensitization and irritation and cover the PICO dressing and secondary fixation strips. These studies indicated that PICO Single Use Negative Pressure Wound Therapy System is safe for its intended use. In addition, residual testing had been performed in accordance with ISO 10993-7 which confirms that PICO dressings and fixation strips comply with the allowable residual limits for ethylene oxide (EO) and ethylene chlorohydrin (ECH).

Electrical Safety and Electromagnetic Compatibility (EMC)

Following the inclusion of the microfuse, PICO Single Use Negative Pressure Wound Therapy System has been tested and assessed respectively by the electrical safety testing agency CSA in accordance with the following electrical safety standards and has been found to be in compliance with these standards:

• IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

• IEC 60601-1-2: 2007 (Third Edition) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, Interpretation Sheet (**Note:** Following an assessment against the requirements of IEC 60601-1-2, it was concluded that no new EMC testing was required to show compliance with the later standard following the inclusion of the microfuse. Therefore no new EMC report was released.)

• IEC 60601-1-6: 2010 (Third Edition) Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability)
• 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

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. Performance testing, service life testing and electrical safety testing has been completed to demonstrate that the modified PICO Single Use Negative Pressure Wound Therapy System is substantially equivalent to the predicate for the intended use.