

MAY 16 2012

**510(k) SUMMARY**  
**PICO Single Use Negative Pressure Wound Therapy System**

1. **Submitter:** Smith & Nephew, Inc.  
970 Lake Carillon Drive, Suite 110  
St. Petersburg, FL 33716
  
2. **Contact:** Terry McMahon  
Director of Regulatory Affairs & Quality, North America  
727-399-3785  
Email: [terry.mcmahon@smith-nephew.com](mailto:terry.mcmahon@smith-nephew.com)
  
3. **Device name:** PICO Single Use Negative Pressure Wound Therapy System  
**Common name:** Negative Pressure Wound Therapy powered suction pump  
**Classification name:** Powered suction pump (21 CFR 878.4780)  
**Product Classification/Code:** Class II, OMP
  
4. **Date Prepared:** May 15, 2012
  
5. **Predicate Device Information:**  
  
NPD 1000 Negative Pressure Wound Therapy System (K080275)  
Kalypto Medical  
6393 Oakgreen Avenue  
Hastings, MN 55033  
  
Renasys Go (K083375)  
Smith & Nephew, Inc.  
St. Petersburg, FL  
  
PICO Single Use Negative Pressure Wound Therapy System (K111170)  
Smith & Nephew, Inc.  
St. Petersburg, FL

## 6. Device Description:

PICO Single Use Negative Pressure Wound Therapy System is a small, lightweight, portable suction device consisting of a 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.

## 7. Intended 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.

Examples of 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.

## 8. Summary of Non-Clinical Testing

The biocompatibility of the PICO Single Use Negative Pressure Wound Therapy System has been demonstrated through assessment according to ISO 10993-1: 2003. *In-vivo* and *in-vitro* tests have been conducted on the dressing and fixation strips of finished product. These tests include cytotoxicity, sensitization and irritation. These studies indicated that the PICO Single Use Negative Pressure Wound Therapy System is safe for its intended use. In addition, residual testing has 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).

Test	Description of Method	Result
Cytotoxicity	<p><b>PICO Dressing</b> In order to determine the cytotoxic potential of the dressing, a Minimum Essential Medium (MEM) elution assay was conducted in accordance with ISO 10993-5.</p>	N to 1:16, all non-cytotoxic (Grade 0)
	<p><b>Secondary Fixation Strips</b> Cytotoxicity testing has been performed on the secondary fixation strips, tested in accordance with ISO 10993-5. The test article extract was diluted in supplemented EMEM 1X and placed onto triplicate confluent monolayers of</p>	N to 1:16, all non-cytotoxic (Grade 0)

Test	Description of Method	Result
	L-929 mouse fibroblast cells at the 100%, 50%, 25% and 5% solutions (v/v).	
Sensitisation	<p><b>PICO Dressing</b> A Guinea Pig Maximisation Test was performed on the dressing in accordance with ISO 10993-10.</p> <p><b>Secondary Fixation Strips</b> A guinea pig maximisation test was performed on the secondary fixation strips in accordance with ISO 10993-10.</p>	<p>Non-sensitising</p> <p>Non-sensitising</p>
Irritation	<p><b>PICO Dressing</b> The dressing was evaluated for irritation in accordance with ISO 10993-10.</p> <p><b>Secondary Fixation Strips</b> Irritation testing has been performed on the secondary fixation strips in accordance with ISO 10993-10.</p>	<p>PII SC = 0.0 PII SC = 0.1 Negligible irritant</p> <p>0.9% NaCl extract: Primary Irritation Index: 0.11 (Negligible)</p>
Ethylene oxide residuals	<p><b>PICO Dressing and Fixation Strips</b> The dressing and strips have been tested in accordance with ISO 10993-7.</p>	<p>Permanent contact limits: Ethylene Oxide &lt;0.1mg/day <b>Complies</b> Ethylene Chlorohydrin &lt;0.4mg/day <b>Complies</b> Tolerable contact limits: Ethylene Oxide 10µg<sup>2</sup>/cm/day <b>Complies</b> Ethylene Chlorohydrin 5mg/cm<sup>2</sup>/cm/day</p>

Additionally, the effects of the dressing wound contact layer (polyurethane) have been assessed during a wound healing study on ALLEVYN Gentle Border dressings. ALLEVYN Gentle Border dressings are a range of currently marketed (by Smith & Nephew) absorbent foam dressings which incorporate an identical top film layer and wound contact layer as the dressing included in the PICO Single Use Negative

Pressure Wound Therapy System. The wound healing study report can be found in the Biocompatibility section.

Testing has been completed in accordance with IEC / UL 60601-1; General Requirements for Safety of Electrical Medical Equipment and IEC 60601-1-2; Electromagnetic Safety Requirements For Electrical Medical Equipment. Software validation has been completed in accordance with IEC 62304 Software for Medical Devices. Reports can be found in the Electromagnetic and Electrical Safety section.

## **9. Conclusion**

Based on results of testing performed the subject device is substantially equivalent to the predicate devices NPD 1000 Negative Pressure Wound Therapy System (K080275), PICO Single Use Negative Pressure Wound Therapy System (K111170) and Renasys Go (K083375).

PICO has similar design characteristics and provides similar functions to NPD 1000 Negative Pressure Wound Therapy System (K080275), PICO Single Use Negative Pressure Wound Therapy System (K111170) and Renasys Go (K083375). The intended use, indications and instructions for use for the subject and predicate devices are similar.

PICO does not raise any new issues of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

MAY 16 2012

Smith and Nephew, Inc.  
% Mr. Terry McMahon  
Director of Regulatory Affairs & Quality, NA  
970 Lake Carillon Drive, Suite 110  
St. Petersburg, Florida 33716

Re: K112127

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 03, 2012  
Received: May 04, 2012

Dear Mr. McMahon:

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

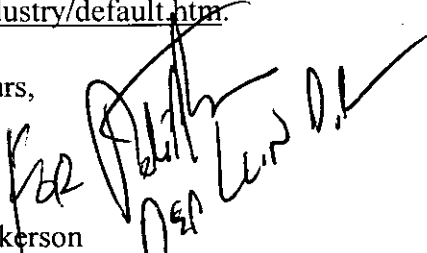
Page 2 – Mr. Terry McMahon

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K112127

Device Name: PICO Single Use Negative Pressure Wound Therapy System

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.

Examples of 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.

Prescription Use   X   AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Daniel Krause for MXM*  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number   K112127