



Food and Drug Administration
10903 New Hampshire Avenue
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December 22, 2015

APR Applied Pharma Research SA
c/o Roger Gray
Donawa Lifescience Consulting SRL
Piazza Albania 10
00153 Rome
Italy

Re: K151168
Trade/Device Name: Nexodyn AOS Wound Care Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 25, 2015
Received: November 27, 2015

Dear Mr. Gray:

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" (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 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,

Binita S. Ashar -S

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)

K151168

Device Name

Nexodyn AOS Wound Care Solution

Indications for Use (Describe)

Nexodyn AOS Wound Care Solution is intended for use under the supervision of healthcare professionals for cleansing, irrigating, moistening and debriding, to remove organic and inorganic debris from partial or full thickness acute and chronic dermal lesions, such as leg ulcers, stasis ulcers, diabetic ulcers, stage I-IV pressure ulcers, post-surgical wounds, grafted and donor sites and 1st and 2nd degree burns, together with cleansing and moistening minor cuts, minor burns, superficial abrasions and minor skin irritations.

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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**510(k) Summary in accordance with 21 CFR 807.92(c)**

Device Name: Nexodyn AOS Wound Care Solution

Type of 510(k) submission: Traditional

Date of Submission: 29 April 2015

Manufacturer: APR Applied Pharma Research SA
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FDA Product Code: FRO

FDA Regulation Number: N/A - Pre-amendment device

FDA Classification Name: Dressing, Wound, Drug

Classification Panel: General and Plastic Surgery

Common Name: Wound Cleansing Solution

FDA Classification: Unclassified

Indications for Use/Intended Use: Nexodyn AOS Wound Care Solution is intended for use under the supervision of healthcare professionals for cleansing, irrigating, moistening and debriding, to remove organic and inorganic debris from partial or full thickness acute and chronic dermal lesions, such as leg ulcers, stasis ulcers, diabetic ulcers, stage I-IV pressure ulcers, post-surgical wounds, grafted and donor sites and 1st and 2nd degree burns, together with cleansing and moistening minor cuts, minor burns, superficial abrasions and minor skin irritations.

**Device Description:**

Nexodyn AOS Wound Care Solution is a clear, liquid solution wound cleanser that helps maintain a moist wound environment by removing dirt, debris and foreign material by the action of the wound cleanser moving across the wound bed. The device contains hypochlorous acid (HClO) acting as a preservative by inhibiting the growth of microorganisms within the solution.

The principle of operation of Nexodyn AOS Wound Care Solution is for the solution to be irrigated across the wound being treated, by using bottles with a spray cap or by sluicing with larger quantity of solution from an open bottle.

The mechanism of action of Nexodyn AOS Wound Care Solution is based on the mechanical action of the solution flowing through the lesion and removing biological and inert materials such as microorganisms, biological debris and environmental dirt.

Nexodyn AOS Wound Care Solution is obtained by electrolysis, carried out on a saline solution, the starting raw materials being water and sodium chloride.

Performance data:

Microbiological efficacy studies carried out with Nexodyn AOS Wound Care Solution have been conducted at the lowest specification level of available chlorine and on three date expired batches to demonstrate that the device specification and labeling claims are met at the end of the device shelf life. The tests were conducted in accordance with USP<51> 'Antimicrobial Effectiveness Testing', including additional requirements specified by FDA, by an independent laboratory, with a starting inoculum of at least 1×10^6 CFU/ml.

Nonclinical testing:

The following nonclinical tests have been performed on the subject device:

- Biocompatibility testing in accordance with the relevant ISO 10993 standards, including:
 - Cytotoxicity (ISO 10993-5);
 - Implantation (ISO 10993-6)
 - Sensitization (ISO 10993-10);
 - Skin Irritation (ISO 10993-10);
 - Acute Systemic Toxicity (ISO 10993-11);
- Stability testing to validate a:
 - 2 year shelf life;
 - 30 day in-use life
- Bulk batch analysis and test, including:
 - appearance;
 - colour;
 - pH;
 - ORP;
 - chlorine assay;
 - chloride assay;
 - conductivity;
 - microbiological tests
- Device batch analysis and test, including:
 - appearance;
 - pH;
 - ORP;
 - conductivity;
 - total chlorine assay;
 - free chlorine assay;
 - chloride assay;
 - microbiological tests.



Substantial equivalence:

The predicate devices selected for comparison with the Nexodyn AOS Wound Care Solution are:

Predicate Device 1: NeuroPhase Skin and Wound Cleanser
 Sponsor: NovaBay Pharmaceuticals, Inc
 510(k) Number:..... K113820
 Clearance Date:..... 8 August 2012
 FDA Product Code: FRO
 Classification Name:..... Dressing, Wound, Drug
 Regulation No: Unclassified

Predicate Device 2: Vashe Wound Therapy Solution
 Sponsor: PuriCore, Inc.
 510(k) Number:..... K123072
 Clearance Date:..... 14 February 2013
 FDA Product Code: FRO
 Classification Name:..... Dressing, Wound, Drug
 Regulation No: Unclassified

The subject device and the predicate devices have many identical or similar properties or features. The only differences that exist are with respect to preservative concentration (i.e. free chlorine content), and solution pH.

The free chlorine content of the predicate devices is higher than Nexodyn AOS Wound Care Solution, being in the range of 100 to 330 ppm versus 40 to 70 ppm.

The pHs of the predicate devices are mildly acidic, being in the range of 3.5 to 6.7. The pH of Nexodyn AOS Wound Care Solution is slightly more acidic, being in the range 2.5 to 3.0.

The safety of Nexodyn AOS Wound Care Solution with this free chlorine content and at this pH has been adequately demonstrated by the results of biocompatibility testing.

The effectiveness of Nexodyn AOS Wound Care Solution has also been demonstrated by successful completion of the tests required by USP <51>, 'Antimicrobial Effectiveness Testing'.

These differences therefore have no significant effect on the safety or effectiveness of the subject device.

Substantial Equivalence Conclusion:

Based on the information contained in this submission, it is concluded that Nexodyn AOS Wound Care Solution is substantially equivalent to the identified predicate devices which are already in interstate commerce within the USA.