K113693

Tuesday, December 04, 2012
2:19 PM

DEC 1 1 2012

510 (k) Summary Ph: 417-725-2116

Seriously Clean LTD Fax: 417-725-4048
1075 W. Kathryn St. Suite 6 Contact: Kip Glass
Nixa, Mo. 65714 Email: kip@nixall.com

Date of Preparation: 12/15/2011

Device Name (proprietary): Nixall™ Wound and Skin Care

Common Name: Wound Cleanser

Classification Name: Wound Dressing

Device Class: Unclassified

Product Code: FRO

Legally Marketed Device for substantial equivalence Comparison:

Oculus Puracyn™ Skin and Wound Cleanser with Preservatives K090206
Vashe™ Wound Cleanser K092232
Anasept™ Antimicrobial Skin and Wound Gel K073547

Device Description:

Nixall™ Wound and Skin Care is a clear solution that aids in the removal of debris and foreign material from the application site. Foreign material and dirt debris are mechanically removed by the action of the wound cleanser moving across the wound bed on the application site with or without the assistance of a suitable wound dressing (i.e. gauze).

Nixall™ Wound and Skin Care will be supplied in High Density Polyethylene (HDPE) bottles of various volumes with dosing (spray) inserts and caps.

Intended Use:

OTC: Nixall™ Wound and Skin Care is intended for over-the-counter use (OTC) of the management of minor skin lacerations, minor abrasions, minor irritations, minor cuts, minor burns and intact skin.
Professional Use: Nixall™ Wound and Skin Care is intended to be used under the supervision of a healthcare professional in the management of wounds such as stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post surgical wounds, first and second degree burns, grafted and donor sites.

These indications are similar to that of the predicate device Oculus Puracyn™ Wound and Skin Care cleared on June 2, 2009.

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Device Technological Characteristics:

Nixall™ Wound and Skin Care is a clear, hypotonic liquid that helps in the removal of the debris and foreign material from the application site. Dirt, debris and foreign materials are removed by the mechanical action of the fluid moving across the wound bed or application site.

Device components are Electrolyzed water 99.5615%, Sodium Chloride (NaCl) 0.4%, Hypochlorous Acid (HOCL) .035% Sodium Hypochlorite (NaOCl) .0035%. The solution preservatives are hypochlorous acid and sodium hypochlorite. The solution contains preservatives to suppress bacterial growth for up to one(1) year after the bottle is opened as refereńced by testing in Appendix A in this application.

Manufacturing:

Nixall™ Wound and Skin Care will be manufactured under the guidelines of current Good Manufacturing Practices (cGMPs) and according to the established manufacturing, quality and product specifications. Process validation has been completed for this device and filling process parameters have been qualified. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode.

Established cGMPs will assure that the device manufactured at Seriously Clean LTD meet all the established specifications prior to the release and is safe and effe ctive for the intended use.

Performance Testing:

Nixall™ Wound and Skin Care has been subjected to in-vitro and in-vivo biocompatibility studies to demonstrate that the device is safe and effe ctive for the indications for use. The preservative effe ctiveness has been supported by USP <51> testing. Other test results have shown inhibited growth of the following bacterium in solution, Proteus mirabilis, Serratia marcescens, including antibiotic resistant Metheicillin Resistant Staphylococcus aureus (MRSA), Vancomycin resistant Enterococcus faecalis (VRE), and Acinetobacter baumannii. The results of the stability study demonstrate that the product is stable and effe ctive for the entire shelf life.

Substantial Equivalence Discussion/Conclusion:

Nixall™ Wound and Skin Care is similar in function and has the same intended use as the predicate device Oculus Puracyn™ Wound and Skin Care (Oculus Innovative Sciences), legally marketed under 510(k) K090206 as a wound dressing.

The indications of use, device description and performance testing described above and in this 510(k) submission concludes that Nixall™ Wound and Skin Care is substantially equivalent to predicate devices, Puracyn™ Skin and Wound Cleanser, 510(k) #K090206, and Vashe™, 510(k) # K092232, and Anasept™, 510(k) #K073547.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Seriously Clean Limited
% Mr. Kip Glass
Chief Operations Officer
1075 West Kathryn Street, Suite 6
Nixa, Missouri 65714

December 11, 2012

Re: K113693
Trade/Device Name: Nixall™ Wound and Skin Care
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 13, 2012
Received: November 13, 2012

Dear Mr. Glass:

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 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,

Peter D. Rumm -S

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

Enclosure

Indications for Use

510(k) Number (if known): K113693

Device Name: Nixall™ Wound and Skin Care

Indications For Use:

Nixall™ Wound and Skin Care, is intended for over the counter and professional use as follows:

OTC: Nixall™ Wound and Skin Care is for the management of , the irrigation of, the moistening of, and lubrication of minor skin abrasions, minor lacerations, minor burns, minor irritations, minor cuts, and intact skin.

Prescription Use: Nixall™ Wound and Skin Care is intended to be used by health care professionals in the management, via debridement of wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, grafted and donor sites.

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

Jiyoung Dang

(Division Sign-Off)
Division of Surgical Devices
510(k) Number _K113693_____

Page 1 of _____