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Attachment 1: 510(k) Summary VASHE® WOUND THERAPY SYSTEM (including the Vashe® Wound Therapy $^{+}$ Solution)

Submitter: PuriCore Inc.
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AUG 09 2010

Contact Person: Dennis Mahoney
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Date Prepared: July 7th, 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. §807.92.

The assigned 510(k) number is : K100918

Device Name (proprietary): Vashe® Wound Therapy System (including Vashe® Wound Therapy^{+} Solution)

Common Name: Wound Cleanser

Classification Name: Solution, saline, (wound dressing)

Classification: Unclassified

Product Code: FRO

Legally Marketed Devices for substantial equivalence comparison:

Vashe® Wound Therapy System (including Vashe® Wound Therapy^{+} Solution) is substantially equivalent to the following devices:

- Anasept™ Antimicrobial Skin and Wound Cleanser and Gel; Anacapa™ Technologies, Inc. K073547, April 23rd, 2008
- Oculus Puracyn™ Skin and Wound Cleanser with Preservatives, Oculus Innovative Sciences, K090206, June 2nd, 2009
- Microcyn™ Wound Gel, K090725, May 20th, 2009, Oculus Innovative Sciences

Description of Device:

The subject device includes a wound cleanser solution that is intended for cleansing, irrigating, and debriding dermal wounds in addition to moistening and lubricating absorbent wound dressings. The mechanical action of fluid moving across the wound provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris. In addition, the subject device contains Free Available Chlorine (FAC) that inhibits contamination within the solution.

Intended Use of the Device:

Vashe® Wound Therapy System (including Vashe® Wound Therapy^{+} Solution) is intended for cleansing, irrigating, moistening, and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings.

These indications are similar to PuriCore predicate device 510(k) #K093155.

Device Technological Characteristics:

Vashe® Wound Therapy System consists of a Vashe® Wound Therapy Generator and Vashe® Wound Therapy+ Solution. The Vashe® Wound Therapy+ Solution is produced from a Vashe® Wound Therapy Generator. The generator is an electromechanical device containing an electromechanical cell, power supply, storage tank, pump, valve, tubing, various mechanical hardware, etc. The Vashe® Wound Therapy^{+} Solution is a clear solution with a controlled pH and containing free available chlorine at a designated concentration (ppm). Cleaning and debriding is caused by the physical action of the of the Vashe® Wound Therapy^{+} Solution moving across the wound while the hypochlorous acid acts as a preservative to ensure no growth of micro-organisms in the solution. In addition, The Vashe® Wound Therapy^{+} Solution also moistens and lubricates absorbent wound dressings.

Manufacturing: The Vashe® Wound Therapy Generator containing the automatic dispense feature will be manufactured according to product specifications and under the guidelines of Good Manufacturing Practices (GMP). Risk analysis has been performed to identify possible failure modes during manufacturing. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode. All established GMPs will assure that the device manufactured at PuriCore meets all the established specifications prior to release and is safe and effective for its intended use.

Performance Testing:

The Vashe® Wound Therapy Generator has been tested for safety and effectiveness in its intended environment. Testing was conducted by Underwriters Laboratories Inc. on the device per UL 61010 and by UL International Demko A/S per EN 61010-1:2001. None of the testing demonstrated any design characteristics that violated the requirements or resulted in any safety hazards. It was concluded that the Vashe® Wound Therapy Generator tested met all relevant requirements of the aforementioned test.

Pre-clinical toxicology evaluations were conducted on the Vashe® Wound Therapy^{+} Solution that demonstrated the solution is biocompatible and safe for clinical use. Testing was performed to determine the potential toxicological effects of exposure to Vashe® Wound Therapy^{+} Solution. The solution showed no irritation or skin sensitization and was not mutagenic in the bacterial mutation genotoxicity assay. In addition, the acute oral toxicity studies showed no toxic effects. In all cases, the Vashe® Wound Therapy^{+} Solution test articles met the requirements of the ISO 10993-5 since the grade was less than a grade 2 (mild reactivity).

Testing was conducted to confirm that the free available chlorine (FAC) contained in the Vashe® Wound Therapy^{+} Solution inhibits contamination within the solution. The Vashe® Wound Therapy^{+} Solution, at its minimum recommended concentration and aged beyond its shelf-life, meets USP 51 requirements. No growth was observed from any of the 21 tests micro-organisms when challenged with aged Vashe solution. Results showed a >99.999% reduction against 20 organisms and 99.995% reduction was observed against the Staphyloccoccus aureus strain (ATCC 6538). Endospore Time Kill Assay results showed that the aged Vashe® Wound Therapy^{+} Solution after 15 seconds contact time produced >99.999% reduction against Clostridium difficile endospores.

Substantial Equivalence Conclusion:

The product is similar in function and intended use to:

- Anasept™ Antimicrobial Skin and Wound Cleanser and Gel manufactured by Anacapa™ Technologies, Inc. that includes among it's labeled uses the management of wounds by maintaining a moist wound environment that is conducive to healing by either absorbing wound exude or donating moisture while delivering antimicrobial sodium hypochlorite which inhibits the growth of microorganisms.
- Oculus Puracyn™ Skin and Wound Cleanser with Preservative manufactured by Oculus Innovative Sciences, that includes among its labeled uses the debridement of wounds. The device also includes a preservative which contains a broad spectrum of antimicrobial agents that inhibit growth of bacteria commonly found in the wound bed.
- Microcyn™ Wound Gel manufactured by Oculus Innovative Sciences, that includes among its labeled uses the management of mechanically or surgically debrided wounds. The device includes FAC that inhibits contamination within the hydrogel.

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

PuriCore Inc.
% Mr. Dennis Mahoney
Director, Quality Assurance and
Regulatory Affairs
508 Lapp Road
Malvern, Pennsylvania 19355

AUG 09 2010

Re: K100918
Trade/Device Name: Vashe® Wound Therapy System
(including Vashe® Wound Therapy+ Solution)
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 04, 2010
Received: August 05, 2010

Dear Mr. Mahoney:

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,

for

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

Enclosure

Attachment 2

Indications for Use Statement

AUG 09 2010

510(k) Number: K100918

Device Name: Vashe® Wound Therapy System (including Vashe® Wound Therapy^{+} Solution)

Indications for Use:

Vashe® Wound Therapy System (including Vashe® Wound Therapy^{+} Solution) is intended for cleansing, irrigating, moistening, and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings.

The Vashe® Wound Therapy System is intended for used by qualified health care personnel trained in its use

Prescription Use XX OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDHR, Office of Device Evaluation (ODE)

David Krause MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100918