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510(k) SUMMARY
(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

WOUND WASH SALINE®

1. Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

DEC 29 2008

BLAIREX LABORATORIES, INC.
1600 W BRIAN DR
COLUMBUS, IN 47201-4047

Phone: (812) 378-1864
Facsimile: (812) 378-1033

Contact Person: Carey Bottom
cbottom@blairex.com

Date Prepared: November 10, 2008

2. Name of Device and Name/Address of Sponsor

Wound Wash Saline®

BLAIREX LABORATORIES, INC.
1600 W BRIAN DR
COLUMBUS, IN 47201-4047

3. Common or Usual Name

Wound Cleanser and Irrigant

4. Classification Name

Dressing, Wound, Drug

5. Description

Wound Wash Saline® is a multi-use, isotonic sterile saline solution packaged in a bag-in-can aerosol system. Actuation of the device (product can) delivers a consistent flow of sterile isotonic saline solution at published safe and effective wound impact pressures of 4 to15 psi [Clinical Practice Guideline Number 15, AHCPR, U.S. Department of Health and Human Services]. The mechanical action of isotonic saline solution moving across

the wound aids in the removal of foreign material, such as dirt and debris, as well as any necrotic tissue, wound exudate and other extraneous matter. No preservatives are added since the finished device is sterilized by gamma irradiation under parameters that have been validated according to ISO/AAMI 11137 requirements [Sterilization of health care products – Requirements for validation and routine control- Radiation sterilization]. Wound Wash Saline® passes the USP<71> Sterility Test. Wound Wash Saline® is an OTC device and will only be labeled for use in cleansing wounds, including the removal of foreign material such as dirt and debris.

6. Predicate Devices

Elta Advanced Wound Wash; Medical Molecular Therapeutics LLC [K073610]

BioDerm Wound Solution; BioDerm Wound Sciences, Inc. [K040683]

Silvion Antibacterial Silver Skin & Wound Moisturizing Solution; Medical Molecular Therapeutics LLC [K063063]

Silvaklenz Antibacterial Silver Skin & Wound Cleanser; Medical Molecular Therapeutics LLC [K063069]

Revera Wound Care; Revalesio Corporation [K070463]

Restore Wound Cleanser; Hollister Incorporated [K040779]

7. Intended Use / Indications for Use

Wound Wash Saline® is intended to be used for cleansing dermal wounds. The label declared indications are: " To cleanse wounds, scrapes and minor burns." The mechanical action of sterile isotonic saline solution irrigating the wound provides for the removal of foreign material such as, but not exclusively, dirt and debris. Wound Wash Saline® can be used to remove tissue debris, wound exudate, and other extraneous matter. Bacteria and tissue metabolic products may also be removed or reduced in level allowing for the natural healing process to take place unimpeded. It may also be used to moisten wound dressings to ease removal from the wound area.

Wound Wash Saline® is indicated for use in cleansing wounds, scrapes, and minor burns

8. Technological Characteristics

Wound Wash Saline® is an aerosol bag-in-can system. The propellant, compressed air, is charged into the container between the bag and the can creating a means to dispense the contents of the bag, isotonic sterile saline solution. The bag is a 4-layer laminate

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system including sandwiched aluminum layer establishing an impermeable barrier between the propellant (compressed air) and the bag contents (sterile isotonic saline). The isotonic saline solution is in contact with either a polypropylene or polyethylene layer. Wound Wash Saline® is a clear, colorless 0.9% sodium chloride solution prepared from sodium choride, USP and purified water, USP. After filling and pressurizing, the device is sterilized by gamma irradiation. The product is tested against established specifications and meets USP sterility requirements.

9. Substantial Equivalence

Wound Wash Saline is as safe and effective as the predicate devices. Wound Wash Saline has the same intended uses, technological characteristics, and basic principles of operation as its predicate devices. The minor technological differences between Wound Wash Saline® and its predicate devices raise no new issues of safety or effectiveness. Thus, Wound Wash Saline® is substantially equivalent to the predicate devices.

This concludes the 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Blairex Laboratories, Inc.
% Carey B. Bottom, Ph.D.
Director, Regulatory Affairs
1600 Brian Drive
Columbus, Indiana 47202-2127

DEC 29 2008

Re: K083355
Trade/Device Name: WOUND WASH SALINE®
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 10, 2008
Received: November 13, 2008

Dear Dr. Bottom:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K083355

Device Name: WOUND WASH SALINE®

Indications for Use:

To cleanse wounds, scrapes, and minor burns.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ____X__ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083355