OCT 17 2005

K042352

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VII. 510(k) summary as described in § 807.92

510(k) Summary

Submitter: **BioDerm Sciences, Inc.**
Enterprise Center
9 Industrial Park Drive, Suite 1N
Oxford, Mississippi 38655
Phone: (301) 216-3912
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Contact Person: Ed Gubish Ph. D. <egubish@healthpathways.com>
Chief Scientific Officer

Preparation Date: June 30, 2005

Proprietary Device Name: BioDerm Sciences Wound Cream

Classification Name: Wound Dressing

Predicate Device:

BioDerm Sciences Wound Solution	K040683
BioDerm Sciences Wound Spray	K042084
Dermagran Wound Management System	K970660

Description: BioDerm Sciences Wound cream is an aqueous-based, acidic zinc/iron-saline cream for external wound management. It aids the body in the healing process by providing a moist, low pH wound environment and providing essential minerals.

BioDerm Sciences Wound cream is similar in chemical composition to the previously approved BioDerm Sciences Wound Solution. Although the zinc chloride and iron chloride contents are similar, the pH value is somewhat higher (ph 3.0-3.4 vs. 2.8); and other trace elements have been added, making it somewhat more comparable in content to BioDerm Sciences Wound Spray. Unlike BioDerm Sciences Wound Solution and Spray, this product is applied as a cream. BioDerm Sciences Wound Cream is supplied in 100 g aluminum tubes. A metal seal at the tip of the tube must be broken in order to use the contents, thus rendering the packaging tamper-resistant. The dressing is applied by squeezing the cream from the tube onto the affected skin.

Intended Use: BioDerm Sciences Wound cream is intended for external management of minor abrasions, lacerations, cuts, scalds, and 1st and 2nd burns. It can be used in conjunction with a conventional dressing that absorbs fluids (i.e. gauze, gel, alginate, foam, hydrocolloid).

BioDerm Sciences Wound cream is contraindicated for use when patients are known to have had allergic reactions to this dressing or its components. It is not suitable for use on third degree burns, or for any wound for which the dermis has been severely damaged or is missing.

Comparison of Technological Characteristics:

The FDA has cleared a number of wet dressings for marketing. All have in common that they are saline solutions based on sodium chloride or metallic salts with a pH less than or equal to 7 (i.e. acidic). They may or may not contain additives such as nutrients.
BioDerm Sciences Wound Cream contains similar proportions and amounts of zinc chloride and iron chloride as the predicate devices BioDerm Sciences Wound Solution and Wound Spray. Like the Dermagran Wound Management System, which is essentially a lanolin-based ointment containing zinc chloride and other nutrients, the water-based BioDerm Sciences Wound Cream is applied and used as a wound cover or filler.

A broad range of chemical compositions is currently available. The chemical composition of BioDerm Sciences Wound Cream is within the range of chemical compositions of these predicate devices and is substantially equivalent in terms of its safety and effectiveness. (See Table 2)

Performance:

A study of various formulations of with varying strength levels of the metallic salts, performed at the University of Miami (Department of Dermatology & Cutaneous Surgery) using a porcine model demonstrated the effectiveness of the solutions contained in the BioDerm Wound Cream as an aid to the body's healing of burns, and partial thickness wounds. No sensitization was demonstrated in tests with guinea pigs and no toxicity was observed in mice receiving intraperitoneal injections. The identical product has been marketed in Europe for fourteen years under the name "**NAWA, Medical Elektrolyt-Salbe S**" with satisfactory performance and no reports of adverse side effects. The Elektrolyt-Salbe is registered as Klasse IIa with registration number: DE/CA65/622-2678.1N4/8.

Conclusions:

When used as directed, BioDerm Sciences Wound Cream is safe and effective as a wound dressing.

Other Information:

This product is intended for sale by or on the order of a physician (or properly licensed practitioner).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

Edward R. Gubish, Ph.D.
Chief Scientific Officer
BioDerm Sciences, Inc.
101 Orchard Ridge Drive, Suite 1N
Gaithersburg, Maryland 20878

Re: K042352
Trade/Device Name: BioDerm Sciences Wound Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 27, 2005
Received: September 28, 2005

Dear Dr. Gubish:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting 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: K042352

Device Name: BioDerm Sciences Wound Cream

Indications for Use:

BioDerm Sciences Wound Cream is intended to externally manage dermal lesions such as lacerations, post-operative (surgical) wounds, partial and full-thickness wounds, 1st and 2nd degree burns and ulcers (diabetic, venous stasis, pressure). It may also be used in conjunction with a dressing that absorbs fluids (i.e. gauze, gel, alginate, foam, hydrocolloid).

Prescription Use__X___ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K042352