K083913

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ChessonLabs

JUL 31 2009

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

510(k) owner's name: Chesson Laboratory Associates, Inc.

Address: 3100 Tower Blvd, Suite 117, Durham, NC 27707

Phone and fax numbers: (919) 419-4900; (919) 419-4923

Name of contact person: Lance L. Swick, PhD

Date of summary: 31 October 2008

K085943

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Name of device:

Trade or proprietary name: to be determined

Common or usual name: liquid bandage

Classification name: liquid bandage; skin protectant

Legally marketed device to which equivalence is claimed: Pro-Derma Liquid Bandage (K063202) or Curad Spray Bandage (K022645)

Description of device:

This product is a liquid polymer in a spray format. The solution is topically applied to the affected area and the carrier solvent evaporates allowing polymerization of the remaining constituents to form a non-toxic, hydrophobic, elastomeric polymer coating that provides a barrier against moisture but that is permeable to oxygen. The intended use is as a liquid bandage, as this coating is biocompatible and forms a tough yet pliable seal, preventing it from cracking and peeling as the skin heals.

Intended use of device: to cover intact skin or minor cuts, scrapes, burns, and irritations of the skin, to help keep them clean and dry and help protect them from infection

Performance characteristics:

The ability of the dried product film to act as a microbial barrier was validated by testing in a modification of ASTM F1608 (Standard Test Method for Microbial Ranking of Porous Packaging Materials) with five species of bacteria. The film formed an effective barrier to all organisms tested.

Biocompatibility of the product was evaluated per ISO-10993 for cytotoxicity, sensitization, and irritation, acute systemic toxicity, genotoxicity, mutagenicity, pyrogenicity, and implantation. Twelve different types of tests were run and the product was shown to be biocompatible.

Bench testing of the bulk formulation and packaged product included molecular weight, purity, and residual components, water content, setting/drying time, viscosity, percent solids, color and particulates, heat of polymerization, as well as moisture vapor transmission rate and tensile strength of the dried film, and distribution/ship tests of the packaged product. All product lots met specifications. Performance characteristics of the product are similar to those of the predicate devices.

Summary Comparison of New Device to Predicate Device

Parameter	Device	Predicate Device	Predicate Device	Predicate Device
Device Name	TBD	Pro-Derma Liquid Bandage	Curad Spray Bandage	New-Skin
Company Name	Chesson Laboratory Associates, Inc	Procurement Technology Systems, LLC	Beiersdorf AG	Medtech Products, Inc (distributor)
510(k) #	TBD	K063202	K022645	Pre-1976

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Class	II	Same	Same	Same
21 CFR number	880.5090	Same	Same	Same
Code	KMF	Same	Same	Same
Product Type	Device	Same	Same	Same
Description	Liquid bandage	Same	Same	Same
Format	Topical spray; Single-use applicator	Single-use applicator	Topical spray	Same
Ancillary components	None	Same	Same	Same
Intended Use	to cover intact skin or minor cuts, scrapes and irritations of the skin, to help keep them clean and dry and help protect them from infection	to cover minor cuts, scrapes and minor irritations of the skin and help protect them from infection	To provide a covering over minor cuts and scrapes that are clean and dry	To protect cuts and scrapes, prevent and protect blisters, helps prevent the formation of calluses, covers painful hangnails
End User	Physician, OTC	OTC	OTC	OTC
Frequency of Use	Once daily or as needed to keep wound covered	Same	Same	Same
Method of Use	Spray on or topical application	Topical application	Spray on	Same
Mechanism of Action	Wound sealant, moisture barrier	Same	Same	Same
Materials / components	Acetone and methyl ethyl ketone solvents, polyetheramine, N,N'-dialkylamino-diphenylmethane, polyether polyol ethylene glycol, propylene glycol, diphenylmethane diisocyanate	2-Octyl and N-Butyl Cyanoacrylate monomers, plasticizer and D&C violet #2 pigment	poly(methylacrylate-isobutene-mono-isopropylmaleate), ethyl acetate, n-pentane, carbon dioxide, menthol	Acetone, Alcohol, Isobutane Propane, Oil of Cloves, Pyroxylin Solution, 8 Hydroxyquinoline
Testing	Biocompatibility per ISO 10993	Same	Same	Unknown

Performance characteristics	Flexible, transparent, water-tight, but allows passage of water vapor; seals out germs	Same	Same	Dries rapidly to form a tough protective cover that is antiseptic, flexible, waterproof, and lets skin breathe. Completely covers the entire wound to keep out dirt and germs

Comparison statement

The Chesson Labs product is similar to the predicate devices in that they are polymers in organic solvents. They provide the same functions as a liquid bandage, are for over-the-counter (OTC) consumer use, have similar claims, and they have the same indications for use. All of these products are liquid solutions applied directly to the wound, which upon contact with the skin dry to form a clear barrier film. They have many of the same functional characteristics, such as water-tightness, water vapor permeability, oxygen permeability, flexibility, and barrier film duration.

Results of biocompatibility and design verification testing provided in the submission have demonstrated that the Chesson Labs Liquid Bandage has the same performance, safety and technical characteristics and therefore raises no new no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Chesson Laboratory Associates, Inc.
% Mr. Scott E. Neuville
President and CEO
3100 Tower Boulevard, Suite 117
Durham, North Carolina 27707

JUL 31 2009

Re: K083913
Trade/Device Name:
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: Class II
Product Code: KMF
Dated: June 3, 2009
Received: June 4, 2009

Dear Mr. Neuville:

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 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/cdrh/mdr/ 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 (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 Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083913

Device Name:

Indications for Use:

To cover intact skin or minor cuts, scrapes, burns, and irritations of the skin, to help keep them clean and dry and help protect them from infection

Prescription Use ___X___
(Part 21 CFR 801 Subpart D)

AND/OR

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

David Krone for MXM

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

K083913

Chesson Laboratory Associates, Inc.

Liquid Bandage

510(k) Number

4-001