K972081

DEC 17 1997

510(k) Summary

Applicant: Michael Byram, CEO, MedLogic Global Corporation, Ste 111, 4815 List Drive, Colorado Springs, CO 80919

1-719-540-8200 (telephone)
1-719-535-8999 (facsimile)

Date: June 3, 1997

Name: SuperSkin®

Classification: Skin Protectant; 21 CFR § 880.5090.

Predicate: 3M No Sting Barrier Film; Bard Protective Barrier Film

Description: SuperSkin® is a topically-applied skin protectant for use on unbroken skin. The patient applies between 2-4 drops of SuperSkin® to the intact skin. The liquid polymerizes to form a thin, flexible coating.

Intended Use: SuperSkin® helps to protect skin exposed to irritation from moisture such as sweat, urine, and digestive juices.

SuperSkin® can also be used on unbroken skin surfaces that are exposed to friction and shear.

Do not apply over broken skin.

Technological Characteristic: SuperSkin® demonstrates appropriate biocompatability and non-toxicity for its intended use; the product is intended for application to skin in a nonsterile aseptic format; and, the product provides equivalent performance in terms of moisture barrier, vapor penetration, shear protection, friction reduction, and chronic irritation to the predicate product.

Data Submitted: Biological testing of medical materials was performed satisfactorily in accordance with the guidelines found in ISO 10993; bioburden assays were performed; and, the product was evaluated for safety in a chronic irritation setting and for performance characteristics for friction reduction and moisture protection in a clinical model.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

Medlogic Global Corporation
% Mr. Jur Strobos
Greenberg & Traurig
1300 Connecticut Avenue, N.W.
Suite 1000
Washington, D. C. 20036

Re: K972081
Trade/Device Name: SuperSkin®
Regulation Number: 21 CFR 880.5090
Regulation Name: Bandage, liquid, skin protectant liquid bandage
Regulatory Class: I (exempt)
Product Code: NEC
Dated: September 29, 1997
Received: September 29, 1997

Dear Mr. Strobos:

This letter corrects our substantially equivalent letter of December 17, 1997.

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 (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.

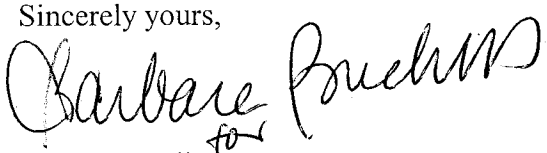
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 continue 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

K972081

K972081

510(k) Number (if known): [redacted]

Device Name: SuperSkin

Indications For Use:

SuperSkin® helps to protect skin exposed to irritation from moisture such as sweat, urine, and digestive juices.

SuperSkin® can also be used on unbroken skin surfaces that are exposed to friction and shear.

Do not apply over broken skin

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972081

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)