K057082

NOV - 8 2005

Safety & Effectiveness: MedTrade Products Skin Protective Barrier Wipe

Classification Name: KMF, 880.5090, Bandage, Liquid

Contact: Jonathan Ranfield - Director, Quality Assurance & Regulatory Affairs

Prepared: April 18, 2005, revised September 6, 2005.

Description: MedTrade Product's Skin Protective Barrier Wipe is a polymeric solution which forms a unique film when applied to the skin. The product is dispersed in a unique non-cytotoxic, water based solution, which dries rapidly.

MedTrade Products Skin Protective Barrier Wipe helps to protect intact or damaged skin from irritation caused by urine and/or fecal incontinence, digestive juices, wound drainage and adhesives. The film is colorless, transparent and possesses good oxygen and moisture vapour permeability.

MedTrade Products Skin Protective Barrier Wipe Wipes are supplied sterile in single use pouches. Packaging will consist of a single dressing in a paper / poly / foil tri laminate pouch, the pouches will then be placed in to a sales carton, with an Instructions For Use Leaflet.

Biocompatibility testing including: Dermal Irritation on the components, Dermal Sensitization on the components, and Cytotoxicity, Irritation & Sensitization on the Skin Protective Barrier Wipe Product has been successfully completed.

The sterile packaged product will be sterilised by gamma irradiation in accordance with the Sterilisation of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilisation, 3rd Edition (ANSI/AAMI/ISO11137-1994) and Microbiological Methods for Gamma Sterilisation (AAMI TIR8-1991). Qualification will be based on Method 1 for dosimetric release with a sterility assurance level of 10^{-6}.

MedTrade Product Skin Protective Barrier Wipe is technologically the same as the substantially equivalent products, 3M No-Sting Barrier Film K955103 & Smith & Nephew No-sting Skin Prep K973228.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Jonathan Ranfield
Director, Quality Assurance & Regulatory Affairs
MedTrade Products Ltd
Electra House
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Crewe, Cheshire CW1 6GL
United Kingdom

Re: K051082
Trade/Device Name: MedTrade Products Skin Protective Barrier Wipe
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: September 6, 2005
Received: September 8, 2005

Dear Mr. Ranfield:

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,

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

Enclosure

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Indications for Use

510(k) Number (if known)

Device Name: MedTrade Products Skin Protective Barrier Wipe

Indications for Use:

MedTrade Products Skin Protective Barrier Wipe is a liquid intended for use as a film-forming product, that upon application to intact or damaged skin forms a long lasting waterproof barrier, which acts as a protective interface between the skin and bodily wastes, fluids and adhesive products. It is intended as a primary barrier against irritation from body fluids.

Prescription Use____X____ AND/OR Over-The-Counter Use__X__
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brennan

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

510(k) Number K051082