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MAY 28 2008

EuroMed

510(k) Summary
SureSkin Silver Bandage

Submitter's name, address, phone and fax numbers

EuroMed Inc.
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Contact Person at EuroMed Inc.

Subhash Chander
Regulatory Affairs Manager
Phone: 845 359 4039 ext. 321
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Date 510(k) Prepared

April 30, 2008

Name of the medical device

Trade Name: SureSkin Silver Bandage
Common Name: Wound Dressing
Classification Name: Occlusive wound dressing (21CFR878.4020)

Occlusive wound dressings with added drugs have not yet been classified by the FDA or given a Product Code. Occlusive wound dressings without drugs have been designated as Class I (general controls) with Product Code "NAD" and exempt from the pre-market notification 510(k) submission requirements. Other wound dressings with antimicrobial properties have not been classified but given the product code, 'FRO".

Legally marketed device to which substantial equivalence is claimed

SureSkin Silver is substantially equivalent in function, construction, and chemical composition to Euromed SureSkin III with Silver Wound Dressings (Rx) cleared by FDA (K050032). The primary purpose of this 510(k) is to seek clearance for Over-The-Counter (OTC) marketing of this dressing with revised indications.

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Device Description

SureSkin Silver bandages are sterile, single-use dressings that consist of silver –containing hydrocolloid adhesive bonded to an outer polyurethane film cover for an antimicrobial effect.

The hydrocolloid adhesive is designed to interact with moisture from the skin and wound surface where it forms a gel and creates a moist wound environment that is known to speed the healing process faster than commonly used bandages

Once the bandage begins to interact with moisture the silver in the adhesive is activated and helps to kill bacteria which are in direct contact with the dressing.

In vitro laboratory testing has demonstrated the dressings antimicrobial effectiveness on fresh clinical isolates of Staph aureus (MRSA), E. coli, and P. aeruginosa.

Intended Use

The SureSkin Silver bandages provide an antimicrobial barrier to microbial colonization in the dressing and help eliminate microbial penetration through the dressing.

SureSkin Silver bandages are indicated for first aid to help minor cuts, scrapes, abrasions, lacerations, blisters, and scalds.

Comparison to predicate device

Company	Euromed, Inc.	Euromed, Inc.
Proprietary Name	SureSkin Silver Bandage	SureSkin III with Silver Wound Dressing
510 (k) Number	Not assigned	K050032
Form	Adhesive Dressing	Adhesive Dressing
Is the device provided sterile?	✓	✓
Is the device intended for single use?	✓	✓
Sterilization Method	Gamma irradiation	Gamma irradiation
Packaging	Pouch	Pouch
Intended Use	Over-the counter use 21 CFR 807 Subpart C	Prescription Use 21 CFR 801 Subpart D

Technological Characteristics comparison with Predicate Device

The SureSkin Silver Bandage is equivalent to the referenced predicate device in that it is composed of identical materials, same antimicrobial characteristics i.e. to provide barrier to microbial colonization in the dressing and reduce microbial penetration through the dressing with an occlusive polyurethane backing.

Non-clinical and Performance Testing

Antimicrobial effectiveness and Microbial Barrier testing was performed on the predicate device and showed that it provides an effective microbial barrier in the dressing. Biocompatibility testing was performed. Test results demonstrated that the device is suitable for its intended use. SureSkin Silver Bandages are identical in formulation, packaging materials and produced under same manufacturing processes to the predicate device. Thus safety and effectiveness is not affected in any manner. The dressing under this submission is identical to the predicate device except over-the-counter use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

Euromed, Inc.
% Subhash Chander
Regulatory Affairs Manager
25 Corporate Drive
Orangeburg, New York 10962

Re: K081274
Trade/Device Name: SureSkin Silver Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 30, 2008
Received: May 5, 2008

Dear Subhash Chander:

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

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 (DGRND/PRSB)
D.O.
f/t:SRA:tlm:5-23-08

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices and Radiological Devices	240-276-0120

Last Updated: Brandi Stuart – 7/9/07

EuroMed

Indications for Use

510(k) Number (if known): K081274

Device Name: SureSkin Silver Bandage

Indications for Use:

SureSkin Silver bandages are indicated for first aid to help minor cuts, scrapes, abrasions, lacerations, blisters and scalds.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for mxm

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

510(k) Number K081274