510(k) Summary
for
Euromed SureSkin III with Silver Wound Dressings

K050032 page 1 of 3

MAY 17 2005

1. SPONSOR

Euromed, Inc.
411 Clinton Ave
Northvale, NJ 07647

Contact Person: Mr. Jarl Jensen
Telephone: 201-750-1840

Date Prepared: January 6, 2005

2. DEVICE NAME

Proprietary Name:	SureSkin™ III with Silver Border Wound Dressing SureSkin™ III with Silver Thin Wound Dressing
Common/Usual Name:	Wound Dressing
Classification Name:	Occlusive Wound and Burn Dressing

3. PREDICATE DEVICES

- Contreet Antimicrobial Wound Dressing K013525
- Xylos Corporation Cell Antimicrobial Wound Dressing K024054
- SureSkin II Wound Dressings K992363

4. DEVICE DESCRIPTION

The SureSkin III with Silver Wound Dressings are identical to the SureSkin II products with the exception that the formulation has been slightly modified to include silver. The SureSkin III formulation includes the same well-known materials that are used in other hydrocolloid wound dressings. Polyurethane film (Border/Thin) backings provide an occlusive covering of the wound. The polyurethane backing (film) is impermeable to water and bacteria. The dressing maintains a constant thickness of hydrocolloid material to the edge of the dressing. The thickness of the hydrocolloid material is decreased at the edges (beveled edges) of the Border

Dressing to improve adherence and reduce the risk of the dressing rolling up. The border itself is a continuation of the hydrocolloid adhesive material. The dressings can be left in place up to seven days if exudate is minimal.

5. INTENDED USE

The SureSkin III with Silver Wound Dressings provide an antimicrobial barrier to microbial colonization in the dressing and reduce microbial penetration through the dressing.

The SureSkin III with Silver Wound Dressings are sterile hydrocolloid wound dressings indicated for the management of lightly to heavily exudating wounds such as pressure sores and leg ulcers, and for the management of dry to lightly exudating wounds such as dermal ulcers, post-operative wounds, superficial wounds, and abrasions. The SureSkin III with Silver Wound Dressings are also suitable for use on second degree burns and donor sites.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The SureSkin III with Silver Wound Dressings manufactured by Euromed, Inc. are composed of a hydrocolloid material and silver, which are in contact with the wound, and an occlusive polyurethane backing. The dressings are identical in design, function and intended use to the commercially available predicate SureSkin II wound dressings. The only difference is the slight change in formulation of the materials.

The technological characteristics of the SureSkin III with Silver Wound Dressings and the predicate products are identical in that they are all dressings that contain a silver component suitable for use on pressure sores, leg ulcers, post-operative wounds, superficial wounds and abrasions. The only differences between the new SureSkin III with Silver products and the predicate devices are slightly different formulations, which are minor and do not affect safety and effectiveness of the device.

7. PERFORMANCE TESTING

Antimicrobial effectiveness and Microbial Barrier testing was performed according to the USP methods and showed that the SureSkin III with Silver Wound Dressings provide an effective microbial barrier in the wound pad. Biocompatibility testing was performed in accordance with the International Organization for Standardization

recommendations. Results of the biocompatibility tests demonstrate that the device is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

Euromed Inc.
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K050032
Trade/Device Name: Euromed SureSkin III with Silver Wound Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 29, 2006
Received: March 30, 2006

Dear Ms. McNamara-Cullinane:

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/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

Indications for Use

510(k) Number (if known): K050032

Device Name: Euromed SureSkin III with Silver Wound Dressings

Indications for Use:

The SureSkin III with Silver Wound Dressings provide an antimicrobial barrier to microbial colonization in the dressing and reduce microbial penetration through the dressing.

The SureSkin III with Silver BORDER wound dressings are indicated for the management of lightly to heavily exudating wounds, such as pressure sores and leg ulcers.

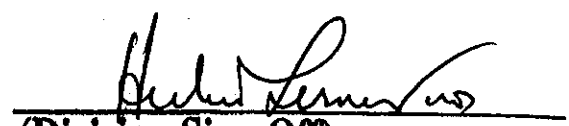
The SureSkin™ III with Silver THIN wound dressings are indicated for the management of dry or lightly exudating wounds, such as dermal ulcers, post-operative wounds, superficial wounds and abrasions.

The SureSkin™ III with Silver wound dressings are also indicated for use on second degree burns and donor sites.

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 K050032