K992363

AUG 12 [illegible]

510(k) Summary
for
SureSkin™ II Hydrocolloid Wound Dressings

1. SPONSOR

Euromed, Inc.
411 Clinton Ave
Northvale, NJ 07647

Contact Person: Mr. Carsten Fredsbo
Telephone: 201-750-1840

Date Prepared: July 14, 1999

2. DEVICE NAME

Proprietary Name:	SureSkin™ II
Common/Usual Name:	Hydrocolloid Wound Dressing
Classification Name:	Occlusive Wound and Burn Dressing

3. PREDICATE DEVICES

SureSkin™ Plus Dressing	K983249
SureSkin™ BORDER Dressing	K960393
SureSkin™ STANDARD Dressing	K960394
SureSkin™ THIN Dressing	K960404
DuoDerm Dressings by Convatec	K863390

4. DEVICE DESCRIPTION

The SureSkin II wound dressings are identical to the SureSkin Plus products with the exception that the formulation has been slightly modified. The SureSkin II hydrocolloid wound dressing formulation includes the same well known materials that are used in other hydrocolloid wound dressings.

The adhesive hydrocolloid surface of these wound dressings is in contact with the wound bed. Polyurethane foam (Standard) and polyurethane film (Border/Thin) backings provide an occlusive covering of the wound. The polyurethane backing (foam or film) is impermeable to water and bacteria. The dressing maintains a constant thickness of hydrocolloid material to the edge of the dressing (Standard and Thin). 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 intended use of the SureSkin II wound dressings are the same as for the original SureSkin™ and SureSkin Plus™ products already cleared by FDA.

The SureSkin II 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. All of the SureSkin™ dressings are suitable for use on second degree burns and donor sites.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

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

7. PERFORMANCE TESTING

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

AUG 12 1999

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

Re: K992363
Trade Name: SureSkin II Hydrocolloid Wound Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: July 14, 1999
Received: July 15, 1999

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992363

Device Name: SureSkin II Hydrocolloid Wound Dressings

Indications for Use:

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

The SureSkin™ II THIN hydrocolloid wound dressing is indicated for the management of dry or lightly exudating wounds, such as dermal ulcers, post-operative wounds, superficial wounds and abrasions.

The SureSkin™ II dressings are also indicated for use on second degree burns and donor sites.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992363

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)