

NOV 25 1998

K983249

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

1. SPONSOR

Euromed, Inc.
411 Clinton Ave
Northvale, NJ 07647

Contact Person: Mr. Carsten Fredsbo
Telephone: 210-750-1840

Date Prepared: September 15, 1998

2. DEVICE NAME

Proprietary Name: SureSkin™ Plus Standard
SureSkin™ Plus Border
SureSkin™ Plus Thin
Common/Usual Name: Hydrocolloid Wound Dressing
Classification Name: Occlusive Wound and Burn Dressing

3. PREDICATE DEVICES

SureSkin™ BORDER Dressing	K960393
SureSkin™ STANDARD Dressing	K960394
SureSkin™ THIN Dressing	K960404
DuoDerm Dressings by Convatec	K863390
DuoDerm Hydroactive Dressing with Border	K853844

4. DEVICE DESCRIPTION

The new SureSkin™ Plus Standard, SureSkin™ Plus Border, and SureSkin™ Plus Thin hydrocolloid wound dressings are identical to the predicate SureSkin™ products except for a slight change in the hydrocolloid materials. The materials are the same except that mineral oil has been added and gelatin has been omitted from the hydrocolloid.

5. INTENDED USE

SureSkin™ Plus STANDARD and Plus BORDER Dressings are sterile hydrocolloid wound dressings indicated for the management of lightly to heavily exudating pressure sores and leg ulcers. The SureSkin™ THIN Plus Dressing is a sterile hydrocolloid wound dressing indicated for the management of dry to lightly exudating dermal ulcers, post-operative wounds, superficial wounds and abrasions. All three of the dressings are suitable for use on post-operative wounds, superficial wounds and abrasions.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The SureSkin® Plus 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™ 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.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983249
Trade Name: SureSkin™ Plus Standard, Border and Thin Hydrocolloid Wound Dressings
Regulatory Class: Unclassified
Product Code: MGP
Dated: September 15, 1998
Received: September 16, 1998

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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.
2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
4. This device may not be labeled as a treatment or a cure for any type of wound.

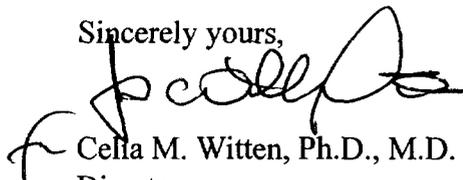
The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP 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,



Cella 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): K983249

Device Name: SureSkin™ Plus Hydrocolloid Wound Dressings

Indications For Use:

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

The SureSkin™ Plus THIN hydrocolloid wound dressing is indicated for the management of dry to lightly exudating wounds, such as pressure sores and leg ulcers.

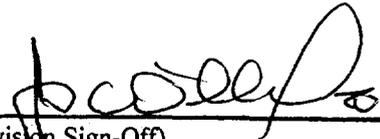
The SureSkin™ Plus dressings are also indicated for use on superficial wounds and abrasions, second degree burns, and donor sites.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K983249

(Optional Format 1-2-96)