

JAN 28 1999

510(k) Summary
Compeed® Psoriasis Dressing

Coloplast Corporation
1955 West Oak Circle
Marietta, Georgia 30062-2249
Date: 1/20/99

1. **Contact Person**

Ms. Sydney Lilly, (770) 281-8260

2. **Name of the Medical Device**

Classification name:	General Hospital and Personal Use Therapeutic Devices
Common/usual name:	Skinprotector
PROPRIETARY name:	Compeed® Psoriasis Dressing

3. **Device Classification**

Unclassified

4. **Statement of Substantial Equivalence**

The Compeed® Psoriasis Dressing is identical to the Compeed® Athletic Dressing manufactured by Coloplast A/S and approved for market under 510(k) K883588.

5. **Intended Use**

The Compeed® Psoriasis Dressing is indicated for use in the management of psoriasis and protection of psoriatic plaques.

6. **Description of Device**

The Compeed® Psoriasis Dressing is a non-sterile, hydrocolloid dressing marketed in Europe for the management of chronic plaque-type Psoriasis.

A comparison Matrix for the Compeed® Psoriasis Dressing versus the Compeed® Athletic Dressing is presented in Table 1.

510(k) Summary Compeed® Psoriasis Dressing - Table 1
 Comparison to Legally Marketed Device

	Compeed® Psoriasis Dressing	Compeed® Athletic Dressing K883588
Device composition	Carboxymethylcellulose, Petroleum hydrocarbon resin, copolymer, Dioctyl adipate, Polyurethane film, silicone paper	Carboxymethylcellulose, Petroleum hydrocarbon resin, copolymer, Dioctyl adipate, Polyurethane film, silicone paper
Shape	triangular	oval
Sizes	one size	small, medium, large
Location of device	Knees and elbows	Foot
Function of device	Skinprotector	Skinprotector
Indication for use	Non-sterile skin protector for use on chronic plaque-like psoriasis	Non-sterile, skin protector to prevent blisters and protect skin from friction that leads to calluses and corns
Sterilization	Non-sterile	Non-sterile
Packaging	Hard plastic casing	Hard plastic casing



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 1999

Ms. M. Sydney Lilly
Coloplast Corporation
1955 West Oak Circle
Marietta, Georgia 30062

Re: K982493
Trade Name: Compeed Psoriasis Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: October 29, 1998
Received: November 2, 1998

Dear Ms. Lilly:

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.

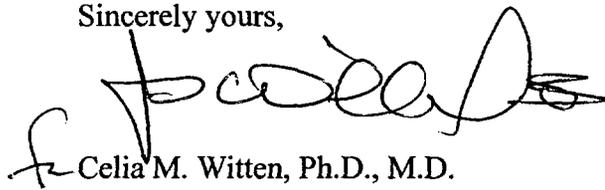
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If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (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,



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): K982493

Device Name: Compeed® Psoriasis Dressing

Indications for Use:

The Compeed® Psoriasis Dressing is indicated for use in the management of psoriasis and protection of psoriatic plaques.

(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 Devices
510(k) Number K982493

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use ✓
(Optional Format 1-2-96)