



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Coloplast Corporation
c/o Mr. Richard A. Hamer
Richard Hamer Associates, Inc.
6401 Meadows West Drive
Ft. Worth, Texas 76132

JUL 29 1997

Re: K971597
Comfeel® Purilon Gel
Regulatory Class: Unclassified
Product Code: MGQ
Dated: April 30, 1997
Received: May 1, 1997

Dear Mr. Hamer:

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

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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.

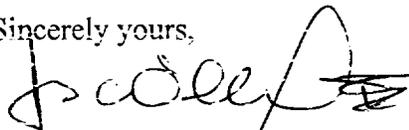
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR),

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,



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

K971597**510 (k) SUMMARY****I. ADMINISTRATIVE**

Submitter: Coloplast, Inc.
1955 West Oak Circle
Marietta, Georgia 30062-2249
USA

JUL 29 1997

Contact Person: Ms. Syd Lilly

Date of Preparation: April 30, 1997

II. DEVICE NAME

Proprietary Name: Comfeel® Purilon Gel
Common Name: Wound Dressing
Classification Name: Hydrogel Wound Dressing

III. PREDICATE DEVICE

IntraSite Gel (Smith & Nephew United, Inc.); K926508.

IV. DEVICE DESCRIPTION

Comfeel® Purilon Gel is an absorbent hydrogel wound dressing composed of calcium alginate, sodium carboxymethylcellulose and purified water. The product is supplied sterile in 15 g and 25 g plastic bellow tubes.

The biocompatibility of Comfeel® Purilon Gel has been established by a primary skin irritation test in rabbits, a cytotoxicity test in guinea pigs, and an *in vitro* cytotoxicity test.

V. INTENDED USE

For use in the management of leg ulcers and pressure sores. The gel provides a moist wound healing environment which encourages natural autolytic debridement.

VI. COMPARISON TO PREDICATE DEVICE

Comfeel® Purilon Gel is similar in composition, function, and intended use to other hydrogel wound dressings, such as IntraSite Gel (Smith & Nephew United, Inc.) K926508.

Accordingly, Coloplast Corporation concluded that Comfeel® Purilon Gel is safe and effective for its intended use and performs at least as well as other hydrogel wound dressings, such as IntraSite Gel.

[Revised: July 18, 1997]

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510(k) Number (if known): K 971597

Device Name: Comfeel® Purilon Gel

Indications for Use:

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[Revised: July 18, 1997]

(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 K971597

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)

Premarket Notification:

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