K983519

DEC 30 1998

510(k) Summary

Comfeel® Seasorb Dressing

Coloplast Corporation
1955 West Oak Circle
Marietta, Georgia 30062-2249
Date: 10/05/98

1. **Contact Person**

   Ms. Sydney Lilly, (770) 281-8260

2. **Name of the Medical Device**

Proposed Classification name:	Hydrophylic Wound and Burn Dressing
Common/usual name:	Topical Wound Dressing
Proprietary name:	Comfeel® Seasorb Dressing

3. **Device Classification**

   The Comfeel® Seasorb Dressing has been classified by the FDA under the proposed heading of Hydrophylic Wound and Burn Dressing as an unclassified device.

4. **Statement of Substantial Equivalence**

   The revised Comfeel® Seasorb Dressing is equivalent to the original Comfeel® Alginate (Seasorb) Dressing, manufactured by Coloplast A/S and approved for market under 510(k) K953497, but with minor alterations.

5. **Intended Use**

   The revised Comfeel® Seasorb Dressing is indicated (under the guidance of a health care professional) for use in management of moderate to heavily exudating wounds, partial and full thickness wounds, including leg ulcers and pressure sores.

6. **Description of Device**

   The revised Comfeel® Seasorb Dressing consists of an absorbent calcium sodium alginate/sodium carboxymethylcellulose xerogel cast onto a high density polyethylene net. The dressing is supplied in three sizes: 4 x 6 cm (3705), and 10 x 10 cm (3710) and 15 x 15 cm (3715). The dressings are packaged in individual pouches and sterilized by ethylene oxide.

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The revised Comfeel® Seasorb Dressing is a modification of Comfeel® alginate (seasorb) dressing (K953497) which consists of 100% alginate. Through adjustment of the formula to 30% carboxymethylcullulose sodium and 70% alginate, the performance of the dressing has been improved measured on softness and absorption capacity.

The revised Comfeel® Seasorb Dressing has been tested and shown no accumulative irritation effects, no evidence of delayed hypersensitivity and is non-cytotoxic (cytotoxicity grade ≤ 2).

A comparison Matrix for the revised Comfeel®Alginate Dressing versus the original Comfeel®Alginate Dressing (K953497) is presented in Section 6.

7. **Predicate Device**

Comfeel®: Alginate (Seasorb) Dressing (Coloplast, Inc. K953497)

	Comfeel® Seasorb Dressing	**Comfeel® Alginate (Seasorb) Dressing**
Statement of Identy	Seasorb Dressing is a sterile Wound Dressing	Comfeel® Alginate (Seasorb) Dressing is a sterile Wound dressing
Device description	The Seasorb Dressing is a highly absorbent wound dressing consisting of an calcium sodium alginate/sodium carboxymethylcellulose Xerogel cast into a high density polyethylene net.	The Comfeel® Alginate (Seasorb) Dressing is a highly absorbent material composed of a Xerogel of calcium sodium alginate cast into a high density polyethylene net.
Sizes	4x6 cm, 10x10 cm, 15x15 cm	4x6 cm, 10x10 cm, 15x15 cm
Use (single, reusable disposable)	Single	Single
Intended use	For management of moderate to heavily exudating Stage I-IV wounds, partial and full thickness wounds, including leg ulcers, pressure sores and burns etc.	For management of (under the guidance of a health care professional) moderate to heavily exudating wounds, including leg ulcers and pressure sores, etc.

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	Comfeel® Seasorb Dressing	Comfeel® Alginate (Seasorb) Dressing
Precautions	May be used on patients with systemic infections when the infectious conditions are under medical control. Seasorb Dressing must be removed prior to radiation treatment of long duration (X-rays, ultrasonic treatment, diathermy and micro waves). Not recommended for use on dry wounds. Do not use on patients with known hypersensitivity to any of the ingredients.	Wounds which are solely or mainly caused by arterial insufficiency or complicated diabetic wounds (primarily lower leg and foot) should be inspected by a physician or nurse regularly. A physician should be consulted before using this product on wounds with a high risk of infection, or on lesions caused by syphilis, tuberculosis, leprosy or cancer. Comfeel®Seasorb (Seasorb) Dressing must be removed prior to the following treatments: radiation, X-rays, ultrasonic treatment, diathermy and micro waves. Wounds with signs of clinical infection, fever and local symptoms such as pain, erythema (redness) or pus should have a bacterial swab examination. Use of this product may be continued at the discretion of a physician. Current systemic antibiotic treatment may be given if indicated. Not recommended for use on dry wounds or third degree burns. Do not use on patients with known hypersensitivity to any of the ingredients.
Sterilization	Sterile	Sterile
Packaging	Polyester pouches laminated with peelable polyethylene prior to sterilization	Polyester pouches laminated with peelable polyethylene prior to sterilization

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 1998

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

Re: K983519
Trade Name: Comfeel Seasorb Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: October 5, 1998
Received: October 8, 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).

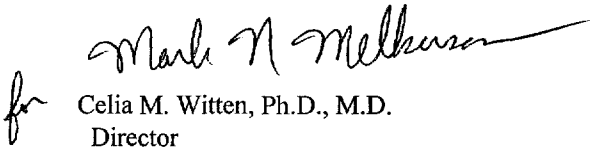
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,



for 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): K983519

Device Name: Comfeel® Seasorb Dressing

Indications for Use:

The Comfeel® Seasorb Dressing is indicated for use (under the guidance of a health care professional) in management of moderate to heavily exudating wounds, partial and full thickness wounds, including leg ulcers and pressure sores.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983519

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

(Optional Format 1-2-96)