

**Biatain Foam Dressing**  
**510(k) SUMMARY**  
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- 1. Submitter:** Coloplast, Inc.  
1955 West Oak Circle  
Marietta, Georgia 30062-2249
- Contact Person:** Ms. Syd Lilly
- Date of Preparation:** 30 July 1998

**2. DEVICE NAME:**

**Proprietary Name:** Biatain Foam Dressing  
**Common name:** Topical Wound Dressing  
**Classification Name:** Wound Dressing

- 3. DEVICE CLASSIFICATION:** Unclassified

- 4. PRODUCT CLASSIFICATION:** 79FRO

**5. PREDICATE DEVICE:**

Allevyn hydrocellular polyurethane dressing (Smith & Nephew Ltd. UK); K871166.

**6. DEVICE DESCRIPTION:**

The Biatain Foam Dressing is a highly absorbent 3-D polymer dressing consisting of a Polyurethane foam with a Polyurethane film printed with inks.

The dressing is supplied in two sizes: 10x10 cm (3410) and 15x15 cm (3413). The dressings are packaged in individual blister packaging and sterilized by  $\beta$ -irradiation.

The topical safety of Biatain Foam Dressing has been established in the following studies:

In the USP Elution Test, diluted and undiluted solutions of the Biatain Foam Dressing (the foam formulation) were shown to be non-cytotoxic (cytotoxicity grad  $\leq 2$ ).

In the intracutaneous test in the rabbit of the Biatain Foam Dressing (the foam formulation) the primary irritation index was 0.0.

In the test for delayed contact hypersensitivity test using the guinea pig maximization test, the Biatain Foam Dressing (the foam formulation) showed no evidence of delayed contact hypersensitivity.

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**7. INTENDED USE:**

For use in the management of low to highly exudating leg ulcers, skin tears, and pressure sores. The dressing can also be used for 2nd degree burns, 2nd degree partial thickness burns, donor sites, post operative wounds and skin abrasions.

**8. COMPARISON TO PREDICATE DEVICE**

Biatain Foam Dressing is similar in composition, function, and intended use to other foam wound dressings, such as Allevyn hydrocellular polyurethane dressing (Smith & Nephew Ltd. UK); K871166. A comparison is presented in the following Table.

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	<b>Biatain Foam Dressing</b>	<b>Allevyn Hydrocellular polyurethane dressing</b>
Device description	Biatain Foam Dressing provides an exudate handling system for low to highly exudating wounds. It is a highly absorbent 3-D polymer dressing. It is especially suitable for use on fragile skin due to the absence of adhesive.	Allevyn Hydrocellular dressing combines an absorbent hydrocellular pad sandwiched between a perforated non-adherent wound contact layer and a waterproof outer film. The absence of the adhesive makes it especially suitable for use on fragile skin.
Sizes	10x10 cm, 15x15 cm	5x5 cm, 10x10cm, 10x20cm, 15x15cm, 20x20 cm
Use (single, reusable, disposable)	Single	Single
Intended use	<p>For use in the management of low to highly exudating leg ulcers, skin tears, and pressure sores. Can also be used for management of 2nd degree burns, 2nd degree partial thickness burns, donor sites, post operative wounds and skin abrasions.</p> <p>It is suitable for use with compression therapy.</p> <p>It can be used for diabetic or infected wounds under the supervision of a health care professional.</p>	<p>For wound management by secondary intention on shallow, granulating wounds.</p> <p>It can cut, especially to dress wounds on heel, elbows and other awkward areas.</p> <p>It can be used in conjunction with compression therapy on venous leg ulcers.</p>
Sterility	Sterile	Sterile



DEC 16 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. M. Sydney Lilly  
Quality Assurance and Regulatory Affairs Manager  
Coloplast Corporation  
1955 West Oak Circle  
Marietta, Georgia 30062-2249

Re: K983163  
Trade Name: Biatain Foam Dressing  
Regulatory Class: Unclassified  
Product Code: MGP  
Dated: October 29, 1998  
Received: November 17, 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).

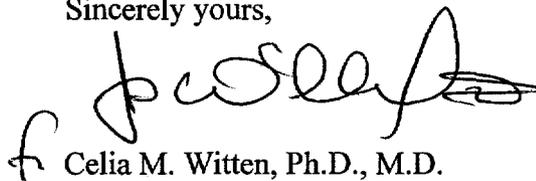
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,



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

K983163

510(k) Number (if known): K983163

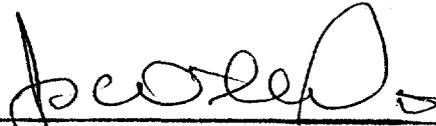
Device Name: Biatain Foam Dressing

Indications for Use:

The Biatain Foam Dressing is indicated for use in the management of low to highly exudating leg ulcers, skin tears, and pressure sores. The dressing can also be used for 2nd degree burns, 2nd degree partial thickness burns, donor sites, post operative wounds and skin abrasions.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K983163

Prescription Use    
 (Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)