

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

2. **DEVICE NAME:**

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

- 3. **DEVICE CLASSIFICATION:** Unclassified

- 4. **PRODUCT CLASSIFICATION NUMBER:** 79FRO

5. **PREDICATE DEVICE:**

Tielle Hydropolymer Dressing (J&J Ltd. UK); 946245.

6. **DEVICE DESCRIPTION:**

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

The dressing is supplied in two size: 120x120 cm (3420) and 180x180cm (3423). The dressings are packaged in individual peel pouches and sterilized by  $\beta$ -irradiation.

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

**The foam formulation:**

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

In the intracutaneous test in the rabbit of the Biatain Foam Adhesive Dressing the primary irritation index was 0.0.

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

**The Adhesive**

The adhesive consists of the same components as Comfeel Plus Transparent Dressing K942283, and no further toxicological studies have been performed.

**7. INTENDED USE:**

For use in the management of low to medium exudating leg ulcers, 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 Adhesive Dressing is similar in composition, function, and intended use to other foam wound dressings, such as Tielle Hydropolymer Dressing (J&J Ltd. UK); K946245. A comparison is presented in the following Table.

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	<b>Biatain Foam Adhesive Dressing</b>	<b>Tielle Hydropolymer Dressing</b>
Device Description	Biatain Foam Adhesive Dressing provides an exudate handling system for low to medium exuding wounds. It is a highly absorbent 3-D polymer dressing. It has a hydrocolloid adhesive and a central 3-D polymer absorbent pad with a waterproof semi-permeable film backing	Tielle Hydropolymer Dressing provides an exudate handling system for low to moderate exuding wounds. It is a highly absorbent dressing. The absorbent material is a synthetic polymer. The island dressing provides a moist wound environment that aids in the wound healing process. During use the absorbent island gently expands as it takes up exudate.
Sizes	120x120 cm, 180x180 cm	7x9 cm, 11x11 cm, 15x15 cm, 15x20 cm, 18x18 cm, 18x18 cm sacrum
Use (single, reusable, disposable)	Single	Single
Intended use	<p>For use in the management of low to medium exuding leg ulcers, 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 can be used for diabetic or infected wounds under the supervision of a health care professional.</p> <p>Is suitable for use under compression bandaging</p>	<p>For use in the management of both chronic and superficial, low to moderate exuding wounds, including the following: Pressure sores (all stages) and venous ulcers.</p> <p>Is suitable for use under compression bandaging</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: K983173  
Trade Name: Biatain Foam Adhesive Dressing  
Regulatory Class: Unclassified  
Product Code: MGP  
Dated: November 4, 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).

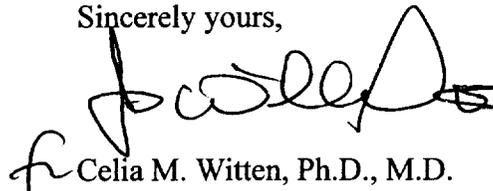
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over the typed name.

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): K983173

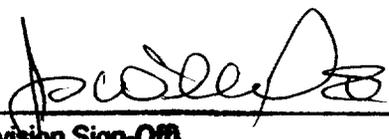
Device Name: Biatain Foam Adhesive Dressing

Indications for Use:

The Biatain Foam Adhesive 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.

(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 K983173

Prescription Use    
(Per 21 CFR 801.109)

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