

K982939



OCT 13 1998

Safety and Effectiveness Summary

Preparation Date: August 17, 1998

Submitter: BioDerm, Inc.
9705 International Court North
St. Petersburg, FL 33716-4807
Phone: (727) 563-9001
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Contact: Marie Teixeira
Director of Quality Assurance and Regulatory Affairs

Device Name: BTF™ Thin Film Wound Dressing

Device Classification Name: Occlusive Wound Dressing

Product Code: MGP

Device Description:

The BioDerm BTF Thin Film Wound Dressing is a sterile thin film dressing which consists of a polyurethane film backed with a hypoallergenic pressure sensitive adhesive. The BTF is a transparent dressing which is permeable to moisture vapor and oxygen and intended to provide a moist wound healing environment to facilitate the normal wound healing process. The BTF Thin Film Wound Dressing provides a barrier to bacteria and external contaminants.

Intended Use:

The BioDerm BTF Wound Dressing is a sterile thin film dressing intended for over-the-counter use and prescription use.

OTC Indications for Use:

Abrasions, lacerations, minor/superficial cuts;
Minor scalds, minor burns;
Minor irritations to the skin

Under the Care of a Health Care Professional:

Leg ulcers, pressure ulcers (stages I and II);
 Surgical wounds (post operative wounds, donor sites);
 1st and 2nd degree burns;
 Cover and protect catheter sites and wounds;
 Securement of medical appliances;
 Catheter securing device;
 Dermal lesions;
 Non-exuding to minimally exuding wounds

Substantially Equivalent Devices:

Smith & Nephew, OpSite
 3M, Tegaderm Transparent Dressing
 Hollister, Simplicare Thin Film Wound Dressing
 J & J, Bioclusive MVP Transparent Dressing
 Innovative Technologies, Transparent Thin Film and Intelligent Thin Film Wound Dressing

Technological Characteristics:

The BioDerm BTF Thin Film Wound Dressing is similar in design, composition and function to the predicate devices listed in the comparative table below.

	BioDerm	Smith & Nephew	3M	Hollister	J & J	Innovative Technologies
Characteristic	BTF Thin Film Wound Dressing	OpSite Wound Dressing	3M Tegaderm and 3M Tegaderm HP Transparent Dressing	Simplicare Thin Film Wound Dressing	Bioclusive MVP Transparent Dressing	Transparent Thin Film and Intelligent Thin Film Wound Dressing
Backing Material	Polyurethane film	Polyurethane film	Polyurethane film	Polyurethane film	Polyurethane film	Polyurethane film
Visibility	Transparent	Transparent	Transparent	Transparent	Transparent	Transparent
Primary Packaging	Peel pouch	Peel pouch	Peel pouch		Peel pouch	Blister pack
Adhesive	Acrylic adhesive Hypoallergenic	Acrylic adhesive Hypoallergenic	Pressure sensitive acrylic adhesive	Pressure sensitive acrylic adhesive	Acrylic adhesive	Pressure sensitive acrylic adhesive
Moisture Vapor Permeability Characteristics	Permeable to water vapor and oxygen	Permeable to water vapor and oxygen	Good oxygen and moisture vapor permeability	High moisture vapor transmission rate Permeable to moisture vapor and oxygen	Permeable to water vapor and oxygen	Permeable to moisture vapor and oxygen
Sterilization	Gamma Irradiation	ETO	Gamma Irradiation	Gamma Irradiation	ETO	Gamma Irradiation
Intended Use	Moist wound healing environment	Moist wound healing environment	Moist wound healing environment	Moist wound healing environment to	Moist wound healing environment	Moist wound healing environment
Bacterial Barrier and	Effective barrier to bacteria and	Impermeable to micro-organisms	Impermeable to liquids and	Barrier to bacteria and external	Impermeable to micro-organisms	Barrier to exogenous moisture

External Contaminate Characteristics	external contaminants	(bacteria) Effective barrier to external contaminants	bacteria Effective barrier to external contamination	contaminates	Effective barrier to external contaminants	and bacteria
Indications for Use	<p>OTC: Abrasions, lacerations, minor/superficial cuts; Minor scalds, minor burns; Minor irritations to the skin</p> <p>Prescription: Leg ulcers, pressure ulcers (stages I and II); Surgical wounds (post operative wounds, donor sites, dermatological); 1st and 2nd degree burns; Cover and protect catheter sites and wounds; Securement of medical appliances; Catheter securing device; Dermal lesions; Non-exuding to minimally exuding wounds</p>	<p>IV/TPN Dressings; Dermal lesions; Scalds; 1st or 2nd degree burns; Donor sites; Post-operative wounds; Abrasions; Lacerations; Surgical incise drape; Partial thickness wounds</p>	<p>Prescription Cover and protect catheter sites and wounds; Secondary dressing; Protective cover; Secure devices to the skin Protective eye covering; Surgical incisions; Skin graft donor sites; Stage I or II pressure ulcers; Superficial wounds (abrasions, skin tears, blister, 1st and 2nd degree burns, chafed skin); Secondary dressing</p>	<p>OTC: Minor burns; Superficial Cuts, lacerations, and abrasions; Minor irritations of the skin</p> <p>Prescription: Non-exuding to minimally exuding wounds; Pressure sores; Lacerations/abrasions; Partial and full thickness wounds; Surgical incisions; Second degree burns; Donor sites; IV sites; Secondary fixation device</p>	<p>Minor burns; Donor sites; Post-operative wounds; Abrasions; Lacerations; Protective cover; Peripheral and central intravenous catheter dressing</p>	<p>OTC: Minor scalds and burns; Superficial wounds such as abrasions, lacerations and cuts</p> <p>Prescription: Partial thickness wounds; Pressure sores; Abrasions; Superficial burns; Lacerations; Donor sites; IV sites; Fixation device; Post-operative surgical wounds; Dermal lesions; Trauma wounds</p>

Biocompatibility:

Biocompatibility testing was performed in accordance with ISO 10993-1: 1995 “Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing” and the Draft Guidance for the Preparation of a Premarket Notification for a Non-interactive Wound Dressing. Testing included: Primary Dermal Irritation, Sensitization, Cytotoxicity, and Repeated Insult Patch Test.

Based upon the results of biocompatibility tests, the device is safe and effective for its intended purpose.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 1998

Ms. Marie Teixeira
Director of Quality Assurance and Regulatory Affairs
BioDerm, Inc.
9705 International Court North
St. Petersburg, Florida 33716-4807

Re: K982939
Trade Name: BTF™ Thin Film Wound Dressing
Regulatory Class: II
Product Code: MGP
Dated: August 19, 1998
Received: August 21, 1998

Dear Ms. Teixeira:

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

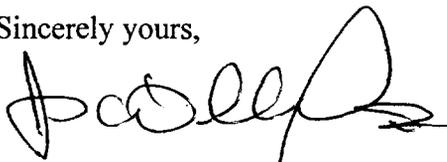
misbranding and adulteration.

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,



f 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

Indications for Use Form

510(k) Number (if known): K982939

Device Name: **BTF™ Thin Film Wound Dressing**

Indications for Use:

The BioDerm BTF Wound Dressing is a sterile thin film dressing intended for over-the-counter use and prescription use. The BioDerm BTF consists of a transparent, polyurethane film backed with a hypoallergenic pressure sensitive adhesive. The BTF is permeable to moisture vapor and oxygen and intended to maintain a moist wound healing environment. A moist wound environment allows atolytic debridement.

OTC Indications for Use:

- ✓ Abrasions, lacerations, minor/superficial cuts;
- ✓ Minor scalds, minor burns;
- ✓ Minor irritations to the skin

Under the Care of a Health Care Professional:

- ✓ Leg ulcers, pressure ulcers (stages I and II);
- ✓ Surgical wounds (post operative wounds, donor sites);
- ✓ 1st and 2nd degree burns;
- ✓ Cover and protect catheter sites and wounds;
- ✓ Securement of medical appliances;
- ✓ Catheter securing device;
- ✓ Dermal lesions;
- ✓ Non-exuding to minimally exuding wounds

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21CFR 801.109)

Over-the Counter Use ✓

J. C. O'Leary
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982939