

Safety & Effectiveness  
 Summary:  
 Classification Name:  
 Common / Usual Name:  
 Contact:  
 Prepared:

Innovative Technologies' Hydrocolloid with Zinc Wound Dressing

79 MGP Wound & Burn, Occlusive  
 Hydrocolloid Wound Dressing  
 Priscilla Whitehead Cox, Director of QA/RA  
 Monday, October 6, 1997

DEC - 1 1997

K973855

Innovative Technologies' Hydrocolloid with Zinc Wound Dressings is a combination of two products with existing 510(k)s: 510(k) #K951499, Dermagran-B™ Hydrophilic Wound Dressing manufactured by Derma Sciences, and 510(k) #K971126, Innovative Technologies' Hydrocolloid & Intelligent Hydrocolloid Wound Dressing.

Innovative Technologies' Hydrocolloid with Zinc Wound Dressings are highly conformable, sterile, primary wound dressings intended to provide an environment ideally suited for the management of moderate to heavily exuding partial to full thickness wounds. The low profile of the of the dressing allows for ease in the use of pressure garments and normal clothing. The hydrocolloid dressing may be left in place until the exuding phase is complete. The wound may then be covered with a breathable polyurethane film such as Innovative Technologies' Film Wound Dressing 510(k) #K9204008 which protects the new tissue from mechanical trauma and maceration.

Dressings are supplied sterile in single use blisters / pouches. Product is gamma irradiated in accordance with EN 552, JEN556, and ANSI / AAMI / ISO11137-1994, Sterilisation Of Health Care Products - Requirements For Validation and Routine Control - Radiation Sterilisation, 3rd Edition, Method 1 for dosimetric release with a sterility assurance level of 10<sup>-6</sup>.

Previous biocompatibility testing and use in the market place have shown safety and effectiveness of the two products.

The Innovative Technologies' Hydrocolloid with Zinc Wound Dressings are similar in design, composition and function to Dermagran-B™ Hydrophilic Wound Dressing manufactured by Derma Sciences, 510(k) #K951499 and Innovative Technologies' Intelligent Hydrocolloid Dressing, 510(k) #K971126.

COMPARATIVE FEATURE

Characteristics	IT Hydrocolloid with Zinc	Derma Sciences Dermagran-B Hydrophilic Wound Dressing	IT Intelligent Hydrocolloid
Composition	Hydrocolloid & polyurethane film /	Modified USP petrolatum based ointment	Hydrocolloid & polyurethane film /
Non-Therapeutic Additives	Zinc / B-6 / Vitamin A	Zinc / B-6 / Vitamin A	N/A
Surface	Extruded and laminated	N/A	Extruded and laminated
Indications For Use	Dermal ulcers, superficial wounds, burns (1st & 2nd degree), donor sites, post operative wounds, protective dressings	Management of venous stasis ulcers, surgical incisions, pressure sores, minor thermal burns, superficial lacerations, cuts and abrasions, other superficial injuries	Dermal ulcers, superficial wounds, burns (1st & 2nd degree), donor sites, post operative wounds, protective dressings
Self adhesive	Yes	No	Yes
Packaging	Blister Pack / Pouch	Poly Tube	Blister Pack / Pouch
Sterilisation Method	Gamma Irradiation	Preservatives	Gamma Irradiation

**Head Office**

Road Three, Winsford Industrial Estate,  
 Winsford,  
 Cheshire CW7 3PD U.K.  
 Tel: 44 (0) 1606 86 3500 Fax: 44 (0) 1606 86 3600  
 Registered in England 2666957



FM 34786  
 ISO 9001  
 EN 46001

**Tarvin Sands Complex**

Tarvin,  
 Cheshire,  
 CH3 8JF U.K.  
 Tel: 44 (0) 1829 741515 Fax: 44 (0) 1829 740456



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Priscilla Whitehead Cox  
Director, Quality Assurance/Regulatory Affairs  
Innovative Technologies, Ltd.  
Road Three, Winsford Industrial Estate  
Winsford, Cheshire  
England CW7 3PD

DEC - 1 1997

Re: K973855  
Innovative Technologies Hydrocolloid with Zinc Wound Dressings  
Regulatory Class: Unclassified  
Product Code: MGP  
Dated: October 7, 1997  
Received: October 9, 1997

Dear Ms. Cox:

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

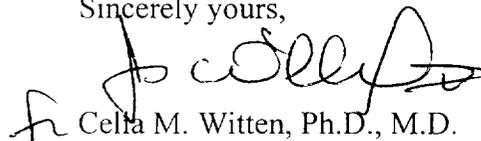
807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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 "C. Witten", is written over the typed name.

Cella 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): K973855

Device Name: Innovative Technologies Hydrocolloid with Zinc Wound Dressings

**Indications For Use:**

Innovative Technologies' Hydrocolloid with Zinc Wound Dressings may be used for the management of wounds including:

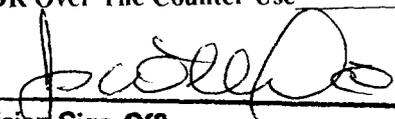
- Partial - full thickness wounds, ie. arterial, venous, diabetic ulcers
- Post-operative surgical wounds
- Superficial burns (1st & 2nd degree)
- Donor Sites
- Trauma Wounds
- Dermal Lesions
- Protective dressing

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   K    
(Per 21 CFR 801.109)

OR Over The Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)

Division of General Restorative Devices  
510(k) Number K973855