

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

Innovative Technologies' Alginate / Zinc Wound Dressing

KMF Liquid Bandage
 Alginate Wound Dressing
 Priscilla Whitehead Cox, Director of QA/RA
 Friday, August 29, 1997

Innovative Technologies' Alginate / Zinc Wound Dressings is a combination of two products with existing 510(k)s: Dermagran™ Zinc-Saline Wet Dressing manufactured by Derma Sciences, 510(k) #K913344 and Innovative Technologies' Al-Gen™ Calcium Alginate Wound Dressing, 510(k) #K953781. Innovative Technologies' Alginate / Zinc Wound Dressings is a 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 non-woven Alginate / Zinc fibre preparation, which includes various sizes of flat dressings and wound packing, reacts with wound exudate to form an dispersable, gelatinous, mass providing for a moist healing environment. The gel may easily be rinsed away from the wound, reducing the potential for delicate peri-wound tissue damage during dressing changes.

Dressings are supplied sterile in single use pouches. Product is gamma irradiated in accordance with 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 10⁻⁶.

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

The Innovative Technologies' Alginate / Zinc Wound Dressings are similar in design, composition and function to Dermagran™ Zinc-Saline Wet Dressing manufactured by Derma Sciences, and Innovative Technologies' Al-Gen™ Calcium Alginate Wound Dressing, 510(k) #K953781.

COMPARATIVE FEATURES

<u>Characteristics</u>	<u>IT Alginate/Zinc</u>	<u>Dermagran™</u>	<u>Al-Gen™</u>
<u>Material</u>	Calcium Alginate / Zinc / B-6	Cotton Gauze / Zinc / B-6 Saline	Calcium Alginate N / A
<u>Non-Therapeutic Additives</u>		Moisturizing Solution	
<u>Surface Integrity</u>	Needled / nip rolled	Woven / Wet	Needled / nip rolled
<u>Indications</u>	Dispersable	Integral	Dispersable
	Moderate to severe exuding wounds, eg. pressure, venous diabetic and arterial ulcers, donor sites, trauma wounds, dermal lesions and incisions, 1st & 2nd degree burns	Management of venous stasis ulcers, surgical incisions, pressure sores, minor thermal burns, superficial lacerations, cuts and abrasions, other superficial injuries	Moderate to severe exuding wounds, eg. pressure ulcers, wounds, leg ulcers, abrasions, donor sites, lacerations incisions, 1st and 2nd degree burns, trauma wounds
<u>Packaging</u>	Paper / Paper or Poly / Poly Pouch	Foil /Foil Pouch	Paper / Paper or Poly / Poly Pouch
<u>Sterilisation Method</u>	Gamma Radiation	Steam	Gamma Radiation



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

OCT 21 1997

Re: K973283
Innovative Technologies Alginate/Zinc Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: August 29, 1997
Received: September 2, 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).

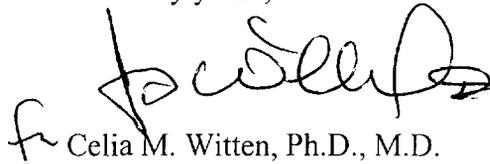
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,



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): K973283

Device name: Innovative Technologies' Alginate / Zinc Wound Dressing

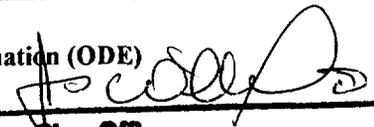
Indications For Use:

Innovative Technologies Alginate / Zinc Wound Dressings may be used for the management of moderate to heavily exuding partial to full thickness wounds such as:

- Pressure Ulcers
- Arterial Ulcers
- Venous Ulcers
- Diabetic Ulcers
- 1st & 2nd Degree Burns
- Donor Sites
- Trauma Wounds
- Dermal Lesions

(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 K973283

Prescription Use X
(Per 21 CFR 801.109)

OR Over The Counter Use _____