



JUN 24 1997

Innovative Technologies Ltd

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

Innovative Technologies' Hydrocolloid & Intelligent Hydrocolloid
Wound Dressings

KMF Liquid Bandage / 79 MGP Wound & Burn, Occlusive
Hydrocolloid Wound Dressing

Priscilla Whitehead, Director of QA/RA

March 25, 1997

Innovative Technologies' Hydrocolloid Wound Dressings, are highly conformable, sterile, primary wound dressings-intended to provide an environment ideally suited for chronic wound management. The dressings are soft conformable hydrocolloid preparations for heavy to light exuding partial-full thickness wounds.

The hydrocolloid preparations react with wound exudate to form an gelatinous mass providing for a moist healing environment. The dressing may easily be lifted away from the wound, reducing the potential for delicate peri-wound tissue damage during dressing changes.

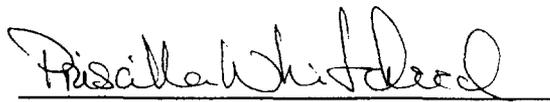
Dressings are supplied sterile in single use blister packs. Product is gamma irradiated in accordance with the Sterilisation Of Health Care Products - Requirements For Validation and Routine Control - Radiation Sterilisation, 3rd Edition (ANSI/AAMI/ISO11137-1995) and Microbiological Methods for Gamma Sterilisation (AAMI TIR8-1991) for qualification of Method 1 for dosimetric release with a sterility assurance level of 10^{-6} .

Biocompatibility testing including cytotoxicity, acute systemic toxicity, skin irritation and sensitisation has been successfully completed per ISO/Tripartite guidelines.

The Innovative Technologies' Hydrocolloid and Intelligent Hydrocolloid Wound Dressings are similar in design, composition and function to Duoderm CGF / Extra Thin Hydrocolloid Dressings manufactured by Convatec.

COMPARATIVE FEATURES

Characteristics	Innovative Technologies	Convatec
Composition	Hydrocolloid & polyurethane film / Hydrocolloid, polyurethane foam & polyurethane film	Hydrocolloid & polyurethane film / Hydrocolloid, polyurethane foam & polyurethane film
Surface	Extruded and laminated	Extruded and laminated
Indications For Use	Dermal ulcers, superficial wounds, burns (1st & 2nd degree), donor sites, post operative wounds, protective dressings	Dermal ulcers, superficial wounds, burns (1st & 2nd degree), donor sites, post operative wounds, protective dressings
Transparent	Yes	Yes
Self adhesive	Yes	Yes
Packaging	Blister Pack	Pouch
Sterilisation Method	Gamma Irradiation	Gamma Irradiation


Priscilla Whitehead, Director QA/RA



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1997

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

Re: K971126
Innovative Technologies' Hydrocolloid & Intelligent Hydrocolloid Wound
Dressings
Regulatory Class: Unclassified
Product Code: MGP
Dated: March 25, 1997
Received: March 27, 1997

Dear Ms. Whitehead:

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



Innovative Technologies Ltd

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510(k) Number (if known) K971126

Device Name: Innovative Technologies Hydrocolloid & Intelligent Hydrocolloid
Wound Dressings

Indications For Use:

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

- Partial - full thickness wounds, ie. arterial, venous, diabetic ulcers
- Post-operative surgical wounds
- Donor Sites
- Trauma Wounds
- Dermal Lesions
- Protective dressing

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971126

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

Concurrence of CDRI, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over The Counter Use _____

(Optional Format 1-2-96)