K973312

IT

Innovative Technologies Ltd

Safety & Effectiveness	Innovative Technologies' Transparent Film and Intelligent Film Dressings
Classification Name:	79 FRO, Dressing
Common / Usual Name:	Film Wound Dressing
Contact:	Priscilla Whitehead Cox, Director of QA/RA
Prepared:	Monday, September 1, 1997

OCT 22 1997

Innovative Technologies' Transparent Film & Intelligent Film Dressings are conformable, sterile wound dressings intended to provide a moist healing environment for partial thickness wounds, eg. pressure sores, abrasions, lacerations, donor sites and superficial burns. The dressings may also be used for IV sites or as secondary fixation devices for products such as alginates, gels and foams used for venous stasis and diabetic ulcers.

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' Film & Intelligent Film Dressings are similar in design, composition and function to Hydroderm Breathable Transparent Dressings 510(k) #K935796. A table of comparative features may be found below.

COMPARATIVE FEATURES

Characteristics	IT Transparent Film	IT Intelligent Film	Hydroderm™
Composition	Polyurethane film and pressure sensitive acrylic adhesive	Polyurethane film and pressure sensitive acrylic adhesive	Polyurethane film and pressure sensitive acrylic adhesive
Adhesive Coverage	100%	Pattern coated 50 ± 30%	Pattern Coated 40%
MVTR g/m²/24hrs	< 2500	3000-15000	8,000
Transparent	Yes	Yes	Yes
Indications For Use	Partial thickness wounds, eg. pressure sores, abrasions, superficial burns, lacerations, donor sites, IV sites, fixation device	Partial thickness wounds, eg. pressure sores, abrasions, superficial burns, lacerations, donor sites, IV sites, fixation device	Partial thickness wounds, eg. pressure sores, abrasions, superficial burns, lacerations, donor sites, IV sites, fixation device
Packaging	Printed Pouch	Printed Pouch	Printed Pouch
Sterilisation Method	Gamma Irradiation	Gamma Irradiation	ETO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT 22 1997

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

Re: K973312
Trade Name: Innovative Technologies Transparent Film & Intelligent Film Dressings
Regulatory Class: Unclassified
Product Code: MGP
Dated: September 1, 1997
Received: September 3, 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 (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

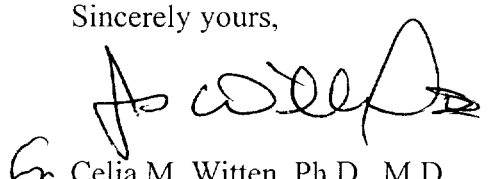
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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,



for 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): K973312

Device name: Innovative Technologies' Transparent Film & Intelligent Film Dressings

Indications For Use:

Innovative Technologies' Transparent Film and Intelligent Film Dressings are indicated for use on partial thickness wounds including:

- Pressure sores
- Superficial burns
- Abrasions
- Lacerations
- Post-operative surgical wounds
- Donor Sites
- Trauma Wounds
- Dermal Lesions
- IV Sites
- ~~Fixation device~~

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973312

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use — X — OR over The Counter Use —