K981753

Attachment 2

JUN 30 1998

Summary of Safety and Efficacy Summary of Innovative Technologies Transparent and Intelligent Film Wound Dressings

Manufacturer:	Innovative Technologies, Limited Road Three, Winsford Industrial Estate Cheshire CW7 3PD, United Kingdom
Regulatory Affairs Contact:	Christopher Oakes, Manager
Telephone:	44 1606 863 500
Date Summary Prepared:	May 13, 1998
Device Trade Name:	Transparent Film & Intelligent Film Wound Dressing.
Common or Usual Name:	Film Wound Dressings
Classification:	Wound Dressings, currently unclassified by FDA.
Description:G	Innovative Technologies Transparent & Intelligent Film Wound Dressings, are conformable, sterile wound dressings intended to provide a moist environment ideally suited for wound management. In particular for partial thickness wounds. Innovative Technologies Transparent Film dressings act as a semi occlusive barrier to exogenous moisture and bacteria whilst still allowing permeability to moisture vapour and oxygen. The film transmits water, but retains other exudate components creating the ideal environment for wound healing and extending the life of the dressing. The Innovative Technologies Intelligent wound dressings utilize an intelligent film to enhance product performance. The semi occlusive dressing acts as a barrier to exogenous moisture and bacteria whilst still allowing permeability to moisture vapour and oxygen. The film transmits water, but retains other exudate components creating the ideal environment for wound healing and extending the life of the dressing.
Intended Use:	Innovative Technologies Transparent Films & Intelligent Films can be used for partial thickness wounds. They can be used for pressure sores, superficial wounds such as minor cuts, lacerations and abrasions, minor scalds and burns (1st & 2nd degree), donor sites, dermal lesions, trauma wounds and post operative surgical wounds. Discontinue use if any infection of the wound is suspected and seek guidance from a health care professional.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1998

Mr. Christopher Oakes
Innovative Technologies, Limited
Road Three
Winsford Industrial Estate
Winsford, Cheshire
United Kingdom CW7 3PD

Re: K981753
Trade Name: Innovative Technologies' Transparent and Intelligent Film Wound Dressing
Regulatory Class: Unclassified
Dated: May 13, 1998
Received: May 18, 1998

Dear Mr. Oakes:

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.

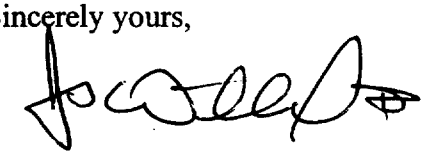
The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing 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,



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): K981753

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 wounds including:

- Minor scalds and burns
- Superficial Wounds such as Abrasions, Lacerations, and cuts

This wound dressing may be also used under the care of a health care professional for such wound as, Pressure sores, post operative surgical wounds, donor sites, trauma wounds and dermal lesions. And for such uses as a IV site and as a secondary fixation device for other wound care products such as alginates, gels and foams used for diabetic ulcers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over The Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981753