

K983303

DEC 9 1998

Attachment 2**Summary of Safety and Efficacy Summary of
Innovative Technologies Hydrocolloid and Intelligent Hydrocolloid 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 883 500
Date Summary Prepared:	December 1st, 1998
Device Trade Name:	Hydrocolloid & Intelligent Hydrocolloid Wound Dressing.
Common or Usual Name:	Hydrocolloid Wound Dressings
Classification:	Wound Dressings, currently unclassified by FDA.
Description:	Highly flexible and conformable gel formula dressings, which absorb wound exudate producing a soft, gel mass which allows easy removal of the dressing reducing the potential for delicate peri-wound tissue damage during dressing changes. Innovative Technologies Intelligent wound dressings utilize an intelligent film which allows moisture to transpire the hydrocolloid whilst providing a barrier to water and bacteria
Intended Use:	Innovative Technologies Hydrocolloids & Intelligent Hydrocolloids can be used for the management of wounds including, minor scalds and burns, superficial wounds such as abrasions, lacerations and minor cuts and as a protective dressing for such uses as minor blisters. This wound dressing may also be used under the care of a health care professional for such wounds as, partial - full thickness wounds i.e. arterial ulcers, venous ulcers and diabetic ulcers, post operative surgical wounds, donor sites. If at any time you are unsure of the above conditions or the type of wound consult a health care professional. Discontinue use if any infection of the wound is suspected and seek guidance from a health care professional
Substantial Equivalence:	Substantial equivalence was provided in 510(k) K971126.
Testing Summary:	Biocompatibility results presented in 510(k) K971126 remain current, no changes to raw materials or components which would require the submission of new toxicity data.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983303
Trade Name: Hydrocolloid and Intelligent Hydrocolloid wound dressings
Regulatory Class: Unclassified
Product Code: MGP
Dated: September 17, 1998
Received: September 21, 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).

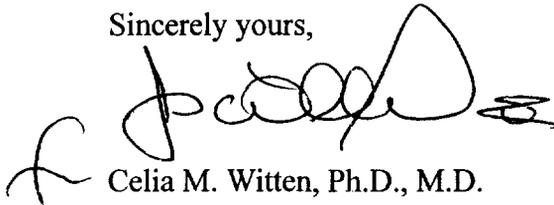
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K983303

510(k) Number (if known): K983303

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:

- Minor Scalds and Minor Burns
- Superficial Wounds such as abrasions, lacerations and minor cuts
- Protective dressing for uses such as minor blisters

This wound dressing may also be used under the care of a health care professional for such wounds as Partial - full thickness wounds i.e. Arterial Ulcers, Venous ulcers, and diabetic ulcers, post operative surgical wounds and donor sites.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR Over The Counter Use X

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K983303