

MAY 27 1998

K980989



Innovative Technologies Ltd

**Summary of Safety and Effectiveness for  
3M™ Tegagen™ HI Alginate Dressing and  
3M™ Tegagen™ HG Alginate Dressing**

**Manufacturer:** Innovative Technologies, Limited  
Road Three, Winsford Industrial Estate  
Cheshire CW7 3PD, United Kingdom

**Regulatory Affairs Contact:** Priscilla Whitehead Cox, Manager

**Telephone:** 44 1606 863 500

**Date Summary Prepared:** March 2, 1998

**Device Trade Name:** 3M™ Tegagen™ HI Alginate Dressing , Product Number 901XX Series and 3M™ Tegagen™ HG Alginate Dressing, Product Number 902XX Series.

**Common or Usual Name:** Alginate Wound Dressings

**Classification:** Wound Dressings, currently unclassified by FDA.

**Description:** These are nonwoven dressings made from 100% pharmaceutical grade calcium alginate harvested from seaweed. The nonwoven alginate fiber dressings are highly conformable, soft, absorbent, sterile, primary wound dressings that become "gels" when they come into contact with wound exudate to form a gelatinous mass which provides a moist healing environment. Use of any dressing, including Tegagen HG and HI alginate dressings, should be part of a well defined protocol for dermal wound management.

**Intended Use:** Tegagen HI and Tegagen HG alginate dressings are intended for use on partial and full thickness wounds with moderate to heavy exudate. They may be used for pressure ulcers, arterial ulcers, venous ulcers, diabetic ulcers, donor sites, trauma wounds, and other dermal lesions. They also are intended to help control minor bleeding. This product is not designed, sold, or intended for use except as indicated.

**Substantial Equivalence:** Substantial equivalence was provided in 510(k) K953781.

**Testing Summary:** Biocompatibility test results presented in Attachment 4 support the safety of this product for it's stated intended use.





MAY 27 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Chris J. Oakes  
Regulatory Affairs Manager  
Innovative Technologies Limited  
Road Three, Winsford Industrial Estate  
Winsford, Cheshire CW7 3PD, United Kingdom

Re: K980989  
Trade Name: 3M Tegagen HI and HG Alginate Dressing  
Regulatory Class: Unclassified  
Product Code: KMF  
Dated: March 2, 1998  
Received: March 16, 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).

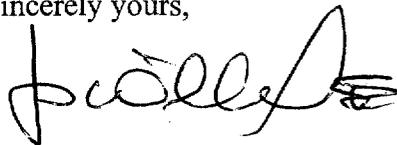
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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

510(k) Number (if known): K980989.

Device name: 3M Tegagen HI & 3M Tegagen HG Alginate Dressings

Indications For Use:

Tegagen HI & HG alginate dressings are intended for use on partial and full thickness wounds with moderate to heavy exudate, eg:

- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Superficial wounds; such as cuts and abrasions
- Donor wounds
- Post-operative wounds
- Trauma wounds
- Dermal lesions

Tegagen HI & HG alginate dressings are also intended to help control minor bleeding.

(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

[Handwritten Signature]

(Optional Format 1-2-96)

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K980989