

SEP 8 1998

K982234

### Summary of Safety and Effectiveness for Innovative Technologies Calcium Alginate Dressing

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

**Regulatory Affairs Contact:** Chris Oakes, Manager

**Telephone:** 44 1606 863 500

**Date Summary Prepared:** June 18, 1998

**Device Trade Name:** Al-Gen Calcium Alginate Wound Dressings.

**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 wound environment. Use of any dressing, including Tegogon HC and HI alginate dressings, should be part of a well defined protocol for dermal wound management.

**Intended Use:** Innovative Technologies Calcium Alginate dressings are intended for use under the supervision of health care professionals on moderate to heavy exudate wounds. They may be used for pressure ulcers, arterial ulcers, venous ulcers, diabetic ulcers, donor sites, trauma wounds, and other dermal lesions. For OTC use on abrasions, lacerations, minor cuts and grazes, minor scalds and minor burns. They also are intended to help control minor bleeding via the adsorbitive properties of the dressing or by the physical application of the dressing to the wound.

If at any time you are unsure of the above conditions or type of wound consult a health care professional.

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

**Testing Summary:** Biocompatibility test results presented in 510(k) K953781 remains 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

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

Re: K982234  
Trade Name: Al- Gen Calcium Alginate Dressing  
Regulatory Class: Unclassified  
Product Code: KMF  
Dated: June 19, 1998  
Received: June 25, 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.

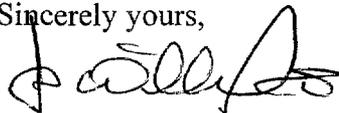
The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing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

  
f 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): K982234

Device name: Innovative Technologies Calcium Alginate Dressings

Indications For Use:

Innovative Technologies Calcium Alginate dressings are intended for use under the guidance of a health care professional on partial and full thickness wounds with moderate to heavy exudate, eg:

- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Superficial wounds
- Donor sites
- Post-operative wounds
- Trauma wounds
- Dermal lesions

And for OTC use on wounds such as, abrasions, lacerations, minor cuts and grazes, minor scalds and burns.

They 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 X  
(Per 21 CFR 801.109)

OR Over The Counter Use X

*J. Willett* (Optional Format 1-2-96)  
 Sign-Off  
 of General Restorative Devices  
 510(k) Number K982234