

AUG 21 1998

K982638

**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: Christopher James Oakes, Manager

Telephone: 44 1606 863 500

Date Summary Prepared: July 21, 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 and K980989.

Testing Summary: Biocompatibility test results are as those
presented in both K953781 and K980989 and
therefore are not re submitted.



MAR 19 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Innovative Technologies, Plc
c/o 3M (Minnesota Mining & Manufacturing)
Ms. Anna E. McRight
Regulatory Affairs Specialist
3M Center, Building 275-3E-08
St. Paul, Minnesota 55144

Re: K982638
Trade Name: 3M Tegagen Hi Alginate Dressing & 3M Tegagen HG Alginate
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 21, 1998
Received: July 29, 1998

Dear Mr. Dagnon:

This letter corrects our substantially equivalent letter of August 21, 1998.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate 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) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act including requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration 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).

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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.

Page 3 – Ms. Anna E. McRight

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K982638

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
- Arterial 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.

Russell Payne
 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K982638

(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 _____

(Optional Format 1-2-96)