

K 980097

Safety & Effectiveness
Summary:
Classification Name:
Common / Usual Name:
Contact:
Prepared:

FlexiGel-G Hydrogel Wound Dressing

MAR - 4 1998

KMF Liquid Bandage
Hydrogel Wound Dressing
Priscilla Whitehead Cox, Director of Regulatory Affairs
Thursday, January 8, 1998

FlexiGel-G Amorphous Hydrogel Wound Dressing, is a clear, non-adherent, amorphous gel provided as a sterile, primary wound dressing.

FlexiGel-G Amorphous Hydrogel Wound Dressing encourages natural debridement through autolysis by gently rehydrating necrotic tissue and is intended to provide a moist healing environment ideally suited for the management of partial to full thickness wounds.

FlexiGel-G Amorphous Hydrogel Wound Dressing is supplied sterile in single use pouches or tubes. The packaged product will be steam sterilised in accordance with Sterilisation Of Health Care Products - Requirements For Validation and Routine Control - Industrial Moist Heat Sterilisation, ANSI / AAMI / ISO11134 - 993. Qualification will be based on the overkill method with a sterility assurance level of 10⁻⁶.

Biocompatibility testing including cytotoxicity, haemolysis, acute systemic toxicity, skin irritation and sensitisation has been successfully completed per ISO/Tripartite guidelines.

FlexiGel-G Amorphous Hydrogel Wound Dressing is similar in design, composition and function to Intrasite™ Gel manufactured by Smith & Nephew.

COMPARATIVE FEATURES

Characteristics	Innovative Technologies	Smith & Nephew
Composition	Guar gum, borax, propylene glycol, water	CMC, propylene glycol, water
Colour	Clear	Clear
Indications For Use	Partial to full thickness wounds eg: arterial, diabetic, pressure and venous ulcers, 1st & 2nd degree burns, trauma wounds and dermal lesions	Shallow and deep open wounds eg: pressure sores, leg ulcers, surgical and malignant wounds, partial thickness burns, scalds, lacerations and grazes.
Fluid Donation	0.22 g/g	0.18 g/g
Fluid Absorption	-0.4 g/g	0.31 g/g
Packaging	Foil pouch / poly tube	Polyethylene bulb applicator

Head Office

Road Three, Winsford Industrial Estate,
Winsford,
Cheshire CW7 3PD U.K.
Tel: 44 (0) 1606 86 3500 Fax: 44 (0) 1606 86 3600
Registered in England 2666957



FM 34786
ISO 9001
EN 46001

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Tarvin,
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CH3 8JF U.K.
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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 1998

Ms. Priscilla Whitehead Cox
Director, Quality Assurance/Regulatory Affairs
Innovative Technologies, Limited
Road Three, Winsford Industrial Estate
Winsford
Cheshire CW7 3PD U.K.

Re: K980097
Trade Name: Flexigel-G Hydrogel Wound Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: January 8, 1998
Received: January 12, 1998

Dear Ms. Cox:

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 enclosures) 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).

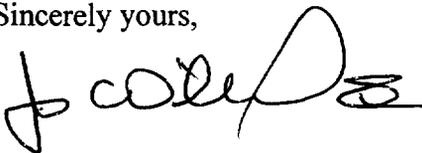
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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

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

Enclosures

510(k) Number (if known): K980097

Revised: February 19, 1998

Device name: FlexiGel-G™ Hydrogel Wound Dressing (Prescription)

Indications For Use:

FlexiGel-G™ Hydrogel Wound Dressing may be used for the management of partial to full thickness wounds e.g.:

- Pressure Ulcers
- Venous Stasis Ulcers
- Diabetic Ulcers
- 1st and 2nd Degree Burns
- Surgical Wounds
- Trauma Wounds
- Dermal Lesions (Cuts, abrasions, etc)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K980097

Prescription Use ~~_____~~
(Per 21 CFR 801.109)

OR Over The Counter Use _____

(Optional Format 1-2-96)

(Optional Format 1-2-96)

510(k) Number (if known): K980097

February 19, 1998

Device name: FlexiGel-G™ Hydrogel Wound Dressing (OTC)

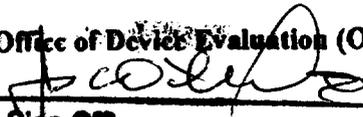
Indications For Use:

FlexiGel-G™ Hydrogel Wound Dressing may be used for the management of wounds such as:

- Superficial cuts
- Abrasions
- Lacerations
- Minor scalds
- Minor burns
- Minor skin irritations

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K980097

Prescription Use _____
(Per 21 CFR 801.109)

OR Over The Counter Use

(Optional Format 1-2-96)