

K990440

AUG 12 1999

510 (k) Summary

Safety and Effectiveness

Summary: Gentell Hydrogel Wound Dressing

Classification Name: 79 MGQ Dressing

Common Name: Hydrogel Wound Dressing

Correspondent: Demetrius Trihoulis

Prepared: January 29, 1999

Gentell hydrogel is an amorphous gel formed with a high molecular weight hydrophilic polymer, water and aloe vera. This primary wound dressing is intended to provide a moist healing environment. Gel may be removed by gentle irrigation, reducing the potential of tissue damage.

Gentell hydrogel is supplied in a multidose eight ounce trigger spray bottle and a four ounce tube. This product is not terminally sterilized and bioburden reduction/stasis is achieved through preservation.

Testing consistent with the Tripartite Biocompatibility Guidance for Medical Devices includes: irritation, sensitization, cytotoxicity and preservative effectiveness test.

Gentell hydrogel wound and burn dressing is similar in design, composition and function to Carrington Dermal Wound Gel (K894541) manufactured by Carrington Laboratories, Inc., and Eutra Gel for Wound Dressing (K932291) manufactured by Swiss American Products, Inc.



AUG 12 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gentell, Inc.
C/O Mark L. Itzkoff
Duane, Morris & Heckscher LLP
1667 K Street N.W., Suite 700
Washington, D.C. 20006

Re: K990440
Trade Name: Gentell Hydrogel Spray Gel, Appligard Squeeze
Regulatory Class: Unclassified
Product Code: MGQ
Dated: June 11, 1999
Received: June 15, 1999

Dear Mr. Itzkoff:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

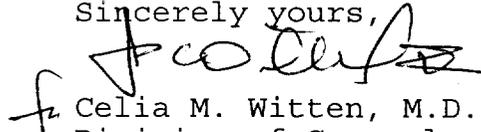
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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.

Page 2 ❖ Mr. Mark L. Itzkoff

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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



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

Enclosure

510(k) Number (if known): _____ **Indications for Use Statement**

Device Name: _____

Indications For Use:

510(k) Number: . K990440
Device Name: Gentell Hydrogel Spray Gel
 Appligard Squeeze Gel

Indications for Use:

- Pressure ulcers, stage II, III & IV wounds
- Venous ulcers
- 1st & 2nd degree burns

(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 K990440

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____