K982116

SEP 8 1998

ITEM 8: SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant:	ConvaTec, A Division of E.R. Squibb & Sons, Inc. 100 Headquarters Park Drive, Skillman, NJ 08558
Contact:	Adrienne McNally, Director, Regulatory Affairs (908) 904-2630
Device:	AQUACEL™ Hydrofiber™ Wound Dressing
Substantially Equivalent Device:	Kaltostat® Wound Dressing

Aquacel Hydrofiber Wound Dressing is a non-absorbable wound dressing. For Over The Counter use, Aquacel may be used for abrasions, lacerations, minor cuts, minor scalds and burns. Under the supervision of a healthcare professional, Aquacel may also be used for wounds such as leg ulcers, pressure ulcers (Stages I-IV), diabetic ulcers, surgical wounds (post-operative, donor sites, dermatological), burns (first and second degree), and the management of surgical or traumatic wounds which have been left to heal by secondary intention. Aquacel may also be used for the local management of wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided, donor sites, and traumatic wounds. Aquacel may be used in the control of minor bleeding.

Aquacel Hydrofiber Wound Dressing is contraindicated for use on individuals with a known sensitivity to the dressing or its components.

Aquacel Hydrofiber Wound Dressing is substantially equivalent to ConvaTec's Kaltostat® Wound Dressing. Both products are equivalent in intended use and dressing characteristics. Both products provide a moist wound healing environment that is supportive of the healing process by aiding autolytic debridement and allowing non-traumatic removal of the dressing without damaging newly formed tissue.

Data/information supporting the safety of Aquacel Hydrofiber Wound Dressing was presented in Premarket Notification K943258. All testing was performed in accordance with Good Laboratory Practice Regulations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 8 1998

Mr. Ameer Ally
Director, Regulatory Affairs
ConvaTec
100 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K982116
Trade Name: Aquacel Hydrofiber Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: May 28, 1998
Received: June 16, 1998

Dear Mr. Ally

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,

for 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

ITEM 1J: INDICATIONS FOR USE STATEMENT:

510(k) Number (if known): K982116

Device Name: AQUACEL™ Hydrofiber™ Wound Dressing

Indications for Use:

For Over The Counter use, Aquacel Hydrofiber Wound Dressing may be used for: abrasions, lacerations, minor cuts and minor scalds and burns. Under the supervision of a health care professional, Aquacel may be used for wounds such as: leg ulcers, pressure ulcers (Stages I-IV), and diabetic ulcers; surgical wounds (post-operative, donor sites, dermatological), burns (first and second degree); management of surgical or traumatic wounds that have been left to heal by secondary intention; local management of wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided, donor sites, and traumatic wounds.

(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 K982116

Prescription Use ____ OR Over-the-Counter Use X
(Per 21 CFR 801.109) (Optimal Format 1-2-96)