3/26/99

K990368

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant:	ConvaTec, A Division of E.R. Squibb and Sons, Inc. 100 Headquarters Park Drive, Skillman, NJ 08558
Contact:	Adrienne McNally, Director, Regulatory Affairs (908) 904-2630
Device:	DuoDERM® Hydroactive Gel Wound Dressing
Substantially Equivalent Device:	Carrasyn® Hydrogel Wound Dressing

For Over-The Counter Use, DuoDERM Hydroactive Gel Wound Dressing may be used for abrasions, lacerations, minor cuts, minor scalds and burns, and skin tears. Under the supervision of a healthcare professional, DuoDERM Hydroactive Gel may be used for the hydration and management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers and skin conditions resulting from radiation dermatitis.

DuoDERM Hydroactive Gel Wound Dressing should not be used on individuals who are sensitive to or who have had an allergic reaction to the gel or its components.

DuoDERM Hydroactive Gel Wound Dressing is substantially equivalent to Carrasyn Hydrogel Wound Dressing. The products are equivalent in intended use and function. Both products provide a moist wound healing environment. DuoDERM Hydroactive Gel Wound Dressing is also capable of absorbing exudate.

Data/information supporting the safety of DuoDERM Hydroactive Gel Wound Dressing was presented in Premarket Notification K931618. 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

MAR 26 1999

Ms. Adrienne McNally
Director, Regulatory Affairs
ConvaTec
A Division of E.R. Squibb & Sons, Inc.
100 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K990368
Trade Name: DuoDERM® Hydroactive® Gel Wound Dressing
Regulatory Class: Unclassifed
Product Code: MGQ
Dated: February 3, 1999
Received: February 8, 1999

Dear Ms. McNally:

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).

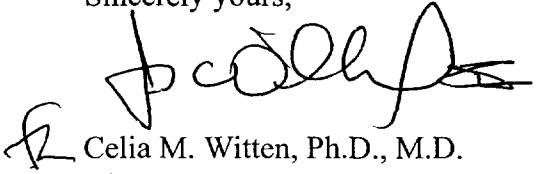
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,



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

K990368

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not Known

Device Name: DuoDERM Hydroactive Gel Wound Dressing

Indications for Use:

For Over-The Counter Use, DuoDERM Hydroactive Gel Wound Dressing may be used for abrasions, lacerations, minor cuts, minor scalds and burns, and skin tears. Under the supervision of a healthcare provider, DuoDERM Hydroactive Gel Wound Dressing may be used for the hydration and management of partial and full thickness wounds such as pressure sores, leg ulcers, diabetic ulcers and skin conditions resulting from radiation dermatitis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990368