

K973688

DEC 23 1997

*510(k) Premarket Notification
DuoDERM® CGF® Control Gel
Formula Border Dressing*

ITEM 8: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The purpose of this 510 (k) Premarket Notification is to request clearance for claims specific to the moist wound environment created by DuoDERM CGF Control Gel Formula Border Dressing . In addition ConvaTec intends to add diabetic ulcers and remove all references to third degree burns from the product labeling.

The concept of DuoDERM CGF Control Gel Formula Border Dressing is not significantly different from other commercially available absorbent dressings intended to cover exudating wounds. DuoDERM CGF Control Gel Formula Border Dressing is indicated for use on chronic wounds-dermal ulcers, including full thickness wounds, pressure ulcers, leg ulcers, diabetic ulcers, acute wounds-superficial wounds (e.g. minor abrasions), second degree burns, donor sites. DuoDERM CGF Control Gel Formula Border Dressing is substantially equivalent to SignaDRESS Hydrocolloid Dressing. The two products are equivalent in intended use and dressing characteristics.

DuoDERM CGF Control Gel Formula Border Dressing is contraindicated for use on individuals with a known sensitivity to the dressing or its components.

Data/information supporting the safety of DuoDERM CGF Control Gel Formula Border Dressing was presented in Premarket Notifications K901155. All testing was performed in accordance with Good Laboratory Practice Regulations.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Adrienne McNally
Senior Manager, Regulatory Affairs
ConvaTec
PO Box 5254
Princeton, New Jersey 08543-5254

DEC 23 1997

Re: K973688 - DuoDERM CGF Control Gel Formula Border Dressing
K973689 - DuoDERM Hydroactive Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: September 19, 1997
Received: September 26, 1997

Dear Ms. McNally:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. These devices may not be labeled for use on third degree burns.
2. These devices may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. These devices may not be labeled as long-term, permanent, or no-change dressings, or as artificial (synthetic) skin.
4. These devices 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 devices and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual

Page 2 - Ms. Adrienne McNally

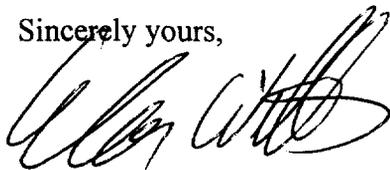
registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval) they may be subject to such additional controls. Existing major regulations affecting your devices 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 submissions 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 devices as described in your 510(k) premarket notifications. The FDA finding of substantial equivalence of your devices 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 devices 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 devices, 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

K 973688

510(k) Premarket Notification
DuoDERM® CGF® Control Gel
Formula Border Dressing

ITEM 1J: INDICATIONS FOR USE STATEMENT

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

Device Name: DuoDERM CGF Control Gel Formula Border Dressing

Indications for Use:

DuoDERM CGF Control Gel Formula Border Dressing is indicated for use on chronic wounds such as pressure ulcers, leg ulcers, diabetic ulcers and acute wounds such as superficial wounds (e.g. minor abrasions), second degree burns and donor sites. DuoDERM CGF Control Gel Formula Border Dressing provides a moist wound 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.

(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 K 973688

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use _____
(Optimal Format 1-2-96)

ConvaTec - A Division of E.R. Squibb & Sons, Inc.
DuoDERM® CGF® Control Gel Formula Border Dressing - A trademark of ConvaTec
SignaDRESS™ Hydrocolloid Dressing - A trademark of ConvaTec 11