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DEC 7 1997

*510(k) Premarket Notification  
CombiDERM™ ACD™ Absorbent  
Cover Dressing*

## **ITEM 8: 510(k) 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, Senior Manager, Regulatory Affairs  
(908)281-2630

**Device:** CombiDERM ACD Absorbent Cover Dressing (Occlusive Wound and Burn Dressing)

**Substantially Equivalent Device:** SignaDRESS Hydrocolloid Dressing K962590

CombiDERM ACD is a moisture retentive dressing and is indicated for use on exuding chronic dermal ulcers, including full thickness wounds such as pressure ulcers, leg ulcers and diabetic ulcers and for acute wounds, such as abrasions, lacerations, biopsies, and open and closed surgical wounds. CombiDERM ACD wicks exudate away from the wound and provides a moist wound environment that is supportive of the healing process. The moist environment aids autolytic debridement and allows non-traumatic removal of the dressing without damaging newly formed tissue.

CombiDERM ACD is contraindicated for use on individuals with a known sensitivity to the dressing or its components.

CombiDERM ACD is substantially equivalent to ConvaTec's SignaDRESS Hydrocolloid Dressing. Both dressings have the identical hydrocolloid adhesive and similar polyurethane backing films. CombiDERM ACD contains an absorbent pad to manage heavy exudate. Both dressings are indicated for acute and chronic wounds and are equivalent in terms of their moist wound healing properties and wound exudate management.

Biocompatibility tests performed on CombiDERM ACD have demonstrated that this product is non-irritating, non-cytotoxic, non-hemolytic and has a weak allergenic potential. All tests were conducted in accordance with Good Laboratory Practices.

*ConvaTec - A Division of E.R. Squibb & Sons, Inc.  
CombiDERM™ ACD™ - A trademark of ConvaTec  
SignaDRESS™ Hydrocolloid Dressing - A trademark of ConvaTec*



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 17 1997

Re: K973717  
CombiDERM™ ACD™ Absorbent Cover Dressing  
Regulatory Class: Unclassified  
Product Code: MGP  
Dated: September 25, 1997  
Received: September 29, 1997

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

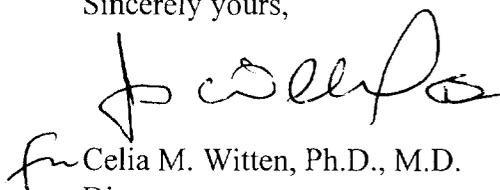
registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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

**1.J: INDICATIONS FOR USE STATEMENT**

K973717

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

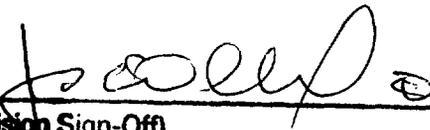
**Device Name:** CombiDERM ACD

**Indications for Use:**

CombiDERM ACD is a moisture retentive dressing and is indicated for use on exuding chronic dermal ulcers including full-thickness wounds, such as pressure ulcers, leg ulcers and diabetic ulcers, and on acute wounds such as abrasions, lacerations, biopsies, and open and closed surgical wounds. The dressing provides a moist wound environment that is supportive of the healing process.

**(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                     K973717                    

Prescription Use   
(Per 21 CFR 801.109)

OR

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