

K97206Z

AUG 14 1997

510(k) Premarket Notification  
ConvaTec Non-Adhesive Dressing

### **Item 8: SUMMARY OF SAFETY AND EFFECTIVENESS**

The purpose of this 510 (k) Premarket Notification is to request clearance to market ConvaTec Non-Adhesive Dressing.

ConvaTec Non-Adhesive Dressing is a sterile, absorbent wound dressing comprised of an absorbent pad containing acrylic polymer affixed to a hydrocolloid layer. The dressing is intended for use on moderately to heavily exuding chronic wounds such as pressure ulcers, leg ulcers and diabetic ulcers and for moderately to heavily exuding acute wounds, such as abrasions, lacerations, biopsies, and open and closed surgical wounds. The dressing may be used alone or in combination with other primary dressings to manage wound exudate.

ConvaTec Non-Adhesive Dressing is contraindicated for use on individuals with a known sensitivity to the dressing or its components.

ConvaTec Non-Adhesive Dressing is substantially equivalent to ConvaTec's CombiDERM™ ACD™. The dressings are equivalent in design, intended use, composition and dressing characteristics.

Biocompatibility tests for ConvaTec Non-Adhesive Dressing have demonstrated that this product is non-irritating, non-cytotoxic, non-toxic, non-hemolytic and has a weak allergenic potential. The results of these studies are enclosed in Item 5 of this application.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

AUG 14 1997

Re: K972062  
ConvaTec Non-Adhesive Dressing  
Regulatory Class: Unclassified  
Product Code: KMF  
Dated: May 30, 1997  
Received: June 3, 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.

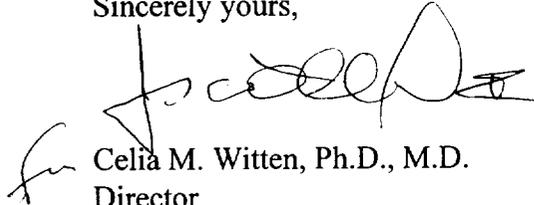
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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

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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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

K972062

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

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

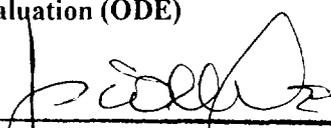
Device Name: ConvaTec Non-Adhesive Dressing

**Indications for Use:**

ConvaTec Non-Adhesive Dressing is indicated for use on moderately to heavily exuding chronic wounds such as pressure ulcers, leg ulcers and diabetic ulcers, and on moderately to heavily exuding acute wounds such as abrasions, lacerations, biopsies, and open and closed surgical wounds. The dressing may be used alone or in combination with other primary dressings to manage wound exudate.

(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 K972062

Prescription Use X  
(Per 21 CFR 801.109)

OR

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