OCT - 1 1997

K972530

ITEM 8: SUMMARY OF SAFETY AND EFFECTIVENESS

The purpose of this 510(k) Premarket Notification is to request clearance to market ConvaTec Odor Control Wound Dressing.

ConvaTec Odor Control Wound Dressing is a sterile, non-adhesive dressing with an absorbent wound contact layer, a water-resistant film layer, an activated charcoal central pad, a non-woven absorbent pad layer and a smooth water- resistant outer film layer.

ConvaTec Odor Control Wound Dressing is indicated for the management of malodorous acute and chronic wounds such as pressure ulcers, leg ulcers and diabetic ulcers. It may be used as a primary dressing for superficial wounds or with deeper wounds as a secondary dressing.

ConvaTec Odor Control Wound Dressing is contraindicated for use on individuals with known sensitivity to the dressing or its components.

ConvaTec Odor Control Wound Dressing is substantially equivalent to Hollister Odor-Absorbent Dressing. Both dressings have essentially the same intended uses and characteristics. ConvaTec Odor Control Wound Dressing is similar in construction and design to Hollister's Odor Absorbent Dressing whereby both dressings are sterile, non-adhesive with a multilayer construction containing a central carbon layer.

Comparative bench testing was conducted on Hollister Odor-Absorbent Dressing and ConvaTec Odor Control Wound Dressing.

ConvaTec Odor Control Wound Dressing has been subjected to biocompatibility testing utilizing the ISO 10993 Part I "Biological Evaluation of Medical Devices" with FDA modified matrix (Guidance effective July 1, 1995). The results of this testing demonstrate that ConvaTec Odor Control Wound Dressing is considered to be non-sensitizing, non-toxic, non-hemolytic and a negligible irritant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

OCT - 1 1997

Re: K972530
ConvaTec Odor Control Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: July 3, 1997
Received: July 7, 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.

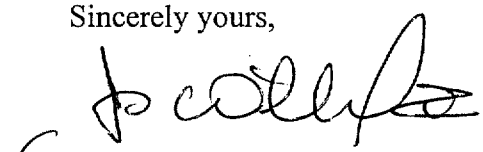
The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

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,



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): Not Known K972530

Device Name: ConvaTec Odor Control Wound Dressing

Indications for Use:

ConvaTec Odor Control Wound Dressing is indicated for the management of malodorous acute and chronic wounds such as pressure ulcers, leg ulcers, and diabetic ulcers. It may be used as a primary dressing for superficial wounds or with deeper wounds as a secondary dressing.

(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 K972530

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use ____
(Optimal Formate 1-2-96)