K974205

FEB 6 1998

ITEM 8: SUMMARY OF SAFETY AND EFFECTIVENESS

The purpose of this 510(k) Premarket Notification is to request clearance to market Knitted Wound Dressing, which be available in three presentations -Standard, WCL and Ribbon and will be labeled as an OTC product.

Knitted Wound Dressing is a sterile gelling gauze. The warp (fibers running top to bottom) consist of viscose yarn, while the wefts (fibers running left right) are a co-spun alginate and viscose.

Knitted Wound Dressing Standard, WCL and Ribbon are comprised of absorbent gelling yarns for the management of acute and chronic wounds, including diabetic ulcers. The design of Standard makes it suitable for shallow or cavity wounds and Ribbon, as a packing strip for cavity wounds, fistulae and sinuses.

Knitted Wound Dressing Standard, WCL and Ribbon are substantially equivalent to KERLIX* Super Sponges manufactured by The Kendall Company, Profore*Wound Contact Layer manufactured by Smith & Nephew Medical Limited and NU GAUZE* manufactured by Johnson & Johnson Medical Inc., respectively.

The products are equivalent in intended use and design. They all are considered general use wound care dressings which can be used in the management of acute and chronic wounds. Knitted Wound Dressing has the added feature of gelling fibers.

Comparative bench testing was conducted on the Knitted Wound Dressing versus its substantially equivalent products. Test results show the products to be equivalent.

Knitted 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 Knitted 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 20850

FEB 6 1998

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

Re: K974205
Knitted Wound Dressing (Standard, WCL, and Ribbon)
Regulatory Class: Unclassified
Product Code: KMF
Dated: November 3, 1997
Received: November 10, 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.

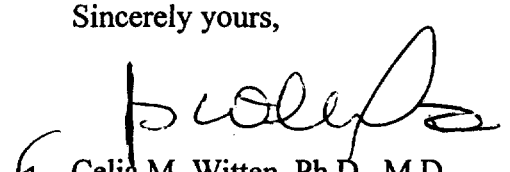
The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing 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

K974205

ITEM 1J: INDICATIONS FOR USE STATEMENT

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

Device Name: Knitted Wound Dressing

Indications for Use:

Knitted Wound Dressing Standard, WCL and Ribbon can be used in the management of acute and chronic wounds, including diabetic ulcers. The design of Standard makes it suitable for shallow or cavity wounds and Ribbon as a packing strip for cavity wounds, fistulae and sinuses.

(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 K974205

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