K980382

MAR - 9 1998

ITEM 10: 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: Nonwoven Compress

Substantially Equivalent Device: Mirasorb Sponges

Non-woven Compress is a sterile wound dressing indicated for use in the management of light to moderately exuding acute wounds such as minor burns, superficial cuts, skin tears, lacerations and abrasions and minor irritations of the skin; and light to moderately exuding chronic wounds such as diabetic ulcers, leg ulcers and pressure ulcers. Non-woven Compress absorbs wound exudate. The absorbent material, on hydration, forms a gel which immobilizes absorbed fluid exudate and helps prevent migration. The wound contact layer is designed to facilitate easy removal from both wet and dry wounds.

Non-woven Compress is contraindicated for use on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.

Non-woven Compress is substantially equivalent to Johnson and Johnson's Mirasorb Sponges. Both products are equivalent in intended use, design and function. They are considered general use wound care dressings which can be used in the management of acute and chronic wounds. The absorbent material in the Non-woven Compress forms a gel which helps retain fluid and exudate.

Comparative bench testing was conducted on Non-woven Compress and Mirasorb Sponges. Test results show the two products to be equivalent.

Non-woven Compress 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 Non-woven Compress is considered to be non-sensitizing, non-cytotoxic, non-hemolytic and a negligible irritant. All tests were conducted in accordance with Good Laboratory Practices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 1998

Ms. Adrienne McNally
Senior Manager, Regulatory Affairs
Convatec
Division of E. R. Squibb & Son
100 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K980382
Trade Name: Non Woven Compress
Regulatory Class: Unclassified
Product Code: KMF
Dated: January 28,1998
Received: February 2, 1998

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

ITEM 3.10: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Not Known~~ K980382

Device Name: Non-woven Compress

Indications for Use:

Non-woven Compress is indicated for use in the management of light to moderately exuding acute wounds such as minor burns, superficial cuts, skin tears, lacerations and abrasions and minor irritations of the skin; and light to moderately exuding chronic wounds such as diabetic ulcers, leg ulcers and pressure ulcers.

(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 K980382

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