

3/3/99

1K984388

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, Director, Regulatory Affairs
(908) 904-2630

Device: HA Absorbent Wound Dressing

**Substantially
Equivalent Device** FIBRACOL Collagen-Alginate Wound Dressing
Knitted Wound Dressing

The purpose of this 510(k) Premarket Notification is to request clearance to market HA Absorbent Wound Dressing.

HA Absorbent Wound Dressing is an absorbent fibrous fleece (F) or rope (R), entirely composed of HYAFF 11p75TM, a benzyl ester of hyaluronic acid.

For over-the-counter use, HA Absorbent Wound Dressing-F may be used for wounds such as: abrasions, lacerations, minor cuts and first degree burns. Under the supervision of a healthcare professional, HA Absorbent Wound Dressing-F may be used for wounds such as: leg ulcers, pressure ulcers (stages I-IV), and diabetic ulcers; surgical wounds (post-operative, donor sites, dermatological), second degree burns; management of wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided, donor sites, and traumatic wounds.

HA Absorbent Wound Dressing-R is indicated for use in the management of deep exuding wounds, sinuses, and fistulae.

HA Absorbent Wound Dressing is contraindicated for use on patients with known sensitivity to the dressing or its components.

HA Absorbent Wound Dressing is substantially equivalent to FIBRACOL Collagen-Alginate Wound Dressing and Knitted Wound Dressing (Ribbon). HA Absorbent Wound Dressing-F is equivalent to FIBRACOL Collagen-Alginate Wound Dressing where both are of a biopolymer composition, absorb wound exudate, and create a moist wound environment supportive of the healing process.

HA Absorbent Wound Dressing-R (Rope) is equivalent to Knitted Wound Dressing (Ribbon) where both are indicated for deep exuding wounds, sinuses and fistulae.

HA Absorbent Wound Dressing has been subject to biocompatibility testing. The results of this testing show that Hyalofill Absorbent Wound Dressing has passed toxicity tests and is considered to be non-toxic, non-hemolytic, a negligible irritant, non-cytotoxic, and has shown to have 0% sensitization potential.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2007

Ms. Adrienne McNally
Director, Regulatory Affairs
ConvaTec
100 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K984388
Trade Name: HA Absorbent Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: December 4, 1998
Received: December 8, 1998

Dear Ms. McNally:

This letter corrects our substantially equivalent letter of March 3, 1999.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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 (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration 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).

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

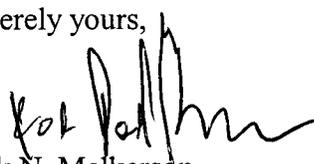
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a prominent initial "M" and a long, sweeping tail.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

