

K990964

MAY 18 1999

510(k) Premarket Notification
SignaDRESS™ DuoDERM® Dressing

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant: ConvaTec, A Division of E.R. Squibb and Sons, Inc.
100 Headquarters Park Drive, Skillman, NJ 08558

Contact: Nancy Woolley, Specialist II, Regulatory Affairs
(908) 904-2571

Device: SignaDRESS™ DuoDERM® Dressing

**Substantially
Equivalent Device:** CombiDERM™ ACD™ Absorbent Cover Dressing (ConvaTec)

SignaDRESS DuoDERM Dressing is a sterile hydrocolloid dressing that, over-the-counter, may be used on abrasions, lacerations, minor cuts, minor scalds and burns and skin tears. Under the supervision of a healthcare professional, SignaDRESS may be used for wounds such as leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology), pressure ulcers (Stage I-IV) and diabetic ulcers, surgical wounds (post-operative wounds, donor sites, dermatological excisions), and burns (first and second degree).

SignaDRESS DuoDERM Dressing is contraindicated for use on individuals with known sensitivity to the dressing or its components.

SignaDRESS DuoDERM Dressing is substantially equivalent to CombiDERM ACD. Both products are equivalent in intended use and dressing characteristics. Both products provide a moist wound healing environment that is supportive of the healing process by aiding autolytic debridement and allowing non-traumatic removal of the dressing without damaging newly formed tissue.

Data/information supporting the safety of SignaDRESS DuoDERM Dressing was presented in Premarket Notification K962590. All testing was performed in accordance with Good Laboratory Practice Regulations.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2007

Ms. Nancy L. Woolley
Specialist II, Regulatory Affairs
ConvaTec, A Division of E.R. Squibb & Sons, Inc.
100 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K990964
Trade Name: SignaDRESS™ DuoDERM® Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: March 19, 1999
Received: March 23, 1999

Dear Ms. Woolley:

This letter corrects our substantially equivalent letter of May 18, 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.

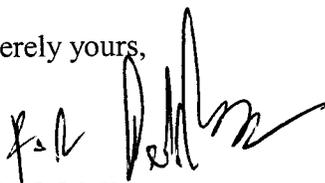
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 3 – Ms. Nancy L. Woolley

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', with a stylized flourish at the end.

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

510(k) Premarket Notification
SignaDRESS™ DuoDERM® Dressing

K990964

INDICATIONS FOR USE STATEMENT

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

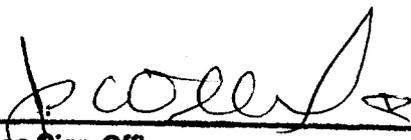
Device Name: SignaDRESS™ DuoDERM® Dressing

Indications for Use:

For Over-The-Counter use SignaDRESS™ DuoDERM® Dressing may be used on abrasions, lacerations, minor cuts, minor scalds and burns, and skin tears. Under the supervision of a health care professional, SignaDRESS may be used for wounds such as leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology), pressure ulcers (Stage I-IV) and diabetic ulcers, surgical wounds (post-operative wounds, donor sites, dermatological excisions), and burns (first and second degree).

(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 K990964

Prescription Use _____
(Per 21 CFR 801.109)

OR

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