January 10, 2025

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

Re: K973716
Trade/Device Name: DuoDERM® Extra Thin CGF® Dressing
Regulatory Class: Unclassified
Product Code: FRO

Dear Ms. McNally:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 17, 1997. Specifically, FDA is updating this SE letter because FDA has better categorized your device technology under product code FRO.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yu-Chieh Chiu, OHT4: Office of Surgical and Infection Control Devices, 301-796-6196, Yu-Chieh.Chiu@fda.hhs.gov.

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1997

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

Re: K973716
DuoDERM® Extra Thin CGF® Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: September 19, 1997
Received: September 29, 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

K973716

1J: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Not Known~~ K973716

Device Name: DuoDERM Extra Thin CGF Dressing

Indications for Use:

DuoDERM Extra Thin CGF Dressings is indicated for use on chronic wounds-dry to lightly exuding dermal ulcers, including diabetic ulcers; acute wounds-surgical wounds (e.g., post operative wounds); and as a protective dressing for areas at risk for skin breakdown. DuoDERM Extra Thin CGF Dressing provides a moist wound environment that is necessary for the healing process.

(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 K973716

Prescription Use ✓
(Per 21 CFR 801.109)

OR

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

ConvaTec - A Division of E.R. Squibb & Sons, Inc.
DuoDERM® Extra Thin CGF ® Dressing-A trademark of ConvaTec
SignaDRESS™ Hydrocolloid Dressing - A trademark of ConvaTec

K973716

DEC 17 1997

ITEM 8: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The purpose of this 510 (k) Premarket Notification is to request clearance for claims specific to the moist wound healing environment created by DuoDERM Extra Thin CGF Dressing. In addition, ConvaTec intends to add diabetic ulcers to the product labeling.

The concept of DuoDERM Extra Thin CGF Dressing is not significantly different from other commercially available absorbent dressings intended to manage exudating wounds. DuoDERM Extra Thin CGF Dressing is indicated for use on chronic wounds-dry to lightly exudating dermal ulcers, including diabetic ulcers, acute wounds-surgical wounds (e.g., post-operative wounds) and as a protective dressing for areas at risk to skin breakdown. DuoDERM Extra Thin CGF Dressing is substantially equivalent to SignaDRESS Hydrocolloid Dressing. The two products are equivalent in intended use and dressing characteristics.

DuoDERM Extra Thin CGF Formula Dressing is contraindicated for use on individuals with a known sensitivity to the dressing or its components.

Data/information supporting the safety of DuoDERM Extra Thin CGF Dressing was presented in Premarket Notifications K891696 and K925990. All testing was performed in accordance with Good Laboratory Practice Regulations.