January 10, 2025

Convatec, A Division of E.R. Squibb & Sons, Inc.
Adrienne McNally
Manager, Regulatory Affairs
100 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K962590
Trade/Device Name: SignaDRESS™ Hydrocolloid Dressing
Regulatory Class: Unclassified
Product Code: FRO

Dear Adrienne 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 September 20, 1996. 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

SEP 20 1996

Ms. Adrienne McNally
Manager, Regulatory Affairs
ConvaTec
A Division of E.R. Squibb & Sons, Inc.
100 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K962590
SignaDRESS™ Hydrocolloid Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: July 1, 1996
Received: July 2, 1996

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 at (301) 443-6597.

Sincerely yours,

Mark N Milhern

for 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

K962590

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

Device Name: SignaDRESS™ Hydrocolloid Dressing

Indications for Use:

SignaDRESS is intended for chronic wounds- pressure ulcers (Stage I-IV) and leg ulcers. SignaDRESS is also indicated for use on acute wounds-surgical wounds (post-operative wounds and donor sites), traumatic wounds (minor abrasions and lacerations), burns (first and second degree), and dermatological excisions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

Mark N Melkerson

for CMW (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K962590

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

SEP 20 1996 K962590

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

The purpose of this 510(k) Premarket Notification is to request clearance to market SignaDRESS Hydrocolloid Dressing.

SignaDRESS is a hydrocolloid dressing consisting of an inner (wound contact) layer of hydrocolloids contained within an adhesive polymer matrix and an outer layer of polyurethane backing film. The dressing also has a product identification mark (ConvaTec registered tear drop trademark) and a visible (SignaDRESS) change indicator guide printed on the film backing.

The dressing adheres to dry and moist tissue and provides a barrier against bacteria and other external contamination as long as the dressing is intact. SignaDRESS is featured with a delivery system that allows clinicians to apply the dressing without touching the adhesive mass. This feature is especially beneficial when gloves are worn to apply the dressing; it minimizes the chance of the gloves sticking to the adhesive mass. A visible change indicator printed on the polyurethane backing film helps simplify wound dressing management for the care giver.

SignaDRESS is intended for chronic wounds-pressure ulcers (Stage I-IV) and leg ulcers. SignaDRESS is also indicated for use on acute wounds-surgical wounds (post-operative wounds and donor sites), traumatic wounds (minor abrasions and lacerations), burns (first and second degree), and dermatological excisions.

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

SignaDRESS is substantially equivalent to Coloplast's Comfeel Plus Ulcer Dressing. Both dressings have essentially the same intended uses, contraindications, precautions, and observations. SignaDRESS is similar in construction and design to Comfeel Plus Ulcer Dressing whereby both dressings consist of a polyurethane backing film printed with a change indicator or measurement grid. Also both dressings are comprised of a hydrocolloid adhesive wound contact layer. Both devices are regulated by the same classification panel. Further classification information is located in Item 1d of this application.

Comparative bench testing was conducted to determine the performance of SignaDRESS and Comfeel Plus Ulcer Dressing. The dressings performed essentially the same with regards to coefficient of friction, absorbency, peel adhesion, and bacterial barrier testing. A summary of the tests and corresponding reports are included in section 5a of this application.

SignaDRESS Hydrocolloid 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 SignaDRESS is considered to be non-toxic, non-cytotoxic, and a negligible irritant. Test reports appear in Item 5 of this application.