January 10, 2025

Hollister, Inc.
Joseph S. Tokarz
Manager, Regulatory Affairs
2000 Hollister Drive
Libertyville, Illinois 60048

Re: K950933
Trade/Device Name: Hollister Hydrocolloid Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO

Dear Joseph S. Tokarz:

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 July 11, 1995. 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 20856

JUL 11 1995

Mr. Joseph S. Tokarz
Manager, Regulatory Affairs
Hollister, Inc.
2000 Hollister Drive
Libertyville, Illinois 60048

Re: K950933
Hollister Hydrocolloid Wound Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: May 9, 1995
Received: May 10, 1995

Dear Mr. Tokarz:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. 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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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K950933

JUL 11 1995

Hollister Incorporated
Hollister Hydrocolloid Wound Care Dressing

JUL 11 1995

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Contact Person
Joseph S. Tokarz
Manager, Regulatory Affairs
(708)680-2849

Date Summary Prepared - February 28, 1995

2. Name of Device:

Hollister Hydrocolloid Wound Dressings

3. Name of Predicate Device(s)

Convatec DuoDERM CGF

4. Description of Device

The Hollister Hydrocolloid Wound Care Dressings are sterile, occlusive dressings. The outer (backing) layer is flexible and protects the wound from contaminants in the external environment The self adhesive hydrocolloid inner layer maintains a moist environment while absorbing excess wound fluid exudate.

1. Indications for Use
   - Dermal ulcers, including full thickness wounds
   - Pressure sore management (Stages I-IV)
   - Leg ulcer management
   - Superficial wounds (minor abrasions)
   - Second degree burns
   - Donor sites

2. Contraindications for Use
   - Third degree burns

5. Statement of Intended Use

The Hollister Hydrocolloid Wound Dressings are intended to provide a moist environment to facilitate the normal wound healing process by avoiding dehydration of the wound bed while absorbing excess wound fluid exudate. It also isolates the wound from the external contaminants.

6. Statement of Technological Characteristics of the Device

A. The Hollister Hydrocolloid Wound Dressings have the same technological characteristics as the predicate device. Listed below is a comparison of the similar and dissimilar features between the Hollister Hydrocolloid Wound Dressings and the predicate device wound dressings.

	Hollister Hydrocolloid Wound Dressings	ConvaTec, DuoDERM C.G.F. Hydrocolloid Wound Dressings
Intended to provide a moist environment to facilitate the normal wound healing process by avoiding dehydration of the wound bed while absorbing excess wound fluid exudate. It also isolates the wound from external contaminates.	Yes	Yes
Dressing formulation:	Hydrocolloid based	Hydrocolloid based
Dressing backing:	Polyether block amide film	Polyurethane foam
Presentation:		
Sizes:	6 various sizes	8 various sizes
Shapes:	Square triangular, rectangular 4 pronged butterfly	Square, triangular, rectangular
Sterile:	Gamma radiation	Gamma radiation

B. Material Biocompatibility: Issues of biomaterial safety or biocompatibility have been addressed based upon the biomaterial history or in separate in-vitro or in-vivo evaluations using licensed commercial reference laboratories. Each assessment was conducted based on principles and guidelines established by various governmental and standard setting organizations among these are the following: Draft International Standard ISO/DIS 10093-1, Triparte Biocompatibility Guidance for Medical Devices and United States Pharmacopeia (USP) The materials used to construct the Hollister Hydrocolloid Wound Dressings are considered biocompatible and suitable for use as a full thickness wound dressing.

C. In-Vivo Porcine Wound Healing Studies: In-vivo porcine wound healing studies (7-day and 29-day) were conducted comparing the Hollister Hydrocolloid Wound Dressings and the predicate device (DuoDERM C.G.F.) as a control. Rates of healing and histopathological evaluations of the wound sites were compared. All wounds tended to heal at similar rates with little difference between the test and

control sites in the healing process observed during macroscopic or microscopic evaluation. There was no evidence of impaired healing using either the proposed device or predicate device.

D. Conclusion: Based on the information presented above and within the body of the 510(k) premarket notification, it is concluded that the Hollister Hydrocolloid Wound Dressings are safe and effective for its intended use. The Hollister Hydrocolloid Wound Dressing is substantially equivalent to the predicate device (DuoDERM C.G.F.).