January 10, 2025

VariSeal Corporation
Owen M. Grant
President
P.O. Box 710
15547 Main Market Road
Parkman, Ohio 44080

Re: K952907
Trade/Device Name: EX-111 Wound Dressings
Regulatory Class: Unclassified
Product Code: FRO

Dear Owen M. Grant:

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 August 7, 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 20850

AUG - 7 1995

Mr. Owen M. Grant
President
VariSeal Corporation
P.O. Box 710
Parkman, Ohio 44080

Re: K952907
EX-111 Wound Dressings
Regulatory Class: Unclassified
Product Code: MGP and KMF
Dated: July 14, 1995
Received: July 18, 1995

Dear Mr. Grant:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. These devices may not be labeled for use on third degree burns.

2. These devices may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.

3. These devices may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. These devices 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 0001 modification in the intended use of the devices 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval) they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices 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 devices as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and permits your devices to proceed to the market, but it does not mean that FDA approves your devices. Therefore, you may not promote or in any way represent your devices or their labeling as being approved by FDA. If you desire specific advice regarding labeling for your devices 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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510(k) Summary

The claims of safety, effectiveness, and substantial equivalence of the **EX-111 Wound Dressing** are supported by the information summarized in the following pages. To allow easy distinction of this summary from the rest of the document that form the actual body of the submission (including exhibits), it has been printed on green pages.

(a) General information

(1) **Submitter Information:**

Owen M. Grant
VSC Healthcare Products
6854 Cochran Road, Solon OH 44139
216-548-7416
Contact Person: **Dr. Debashish Chakravarthy**
216-548-7416

This summary was prepared on **6/10/1995**.

(2) **Device Name**: EX-111 Wound Dressing
Common Name: Hydrocolloid Wound Dressing
Classification Name: Occlusive Wound Dressing

Device Classification: According to the FDA document dated September 1, 1993, entitled "Draft Guidance for the Preparation of a Premarket Notification for a Wound Dressing", these products are unclassified. The above document was published by the Plastic and Reconstructive Surgery Devices Branch, Division of General and Restorative Devices, Office of Device Evaluation.

(3) **Equivalence to Comparable Marketed Products (Claim of Substantial Equivalence):** EX-111 has the same intended use as the various predicate devices listed below, with the corresponding 510(k) numbers, where available.

1. **DuoDERM® Hydroactive® Dressing**, distributed by Convatec, Princeton, NJ 08543-5240. 510 Access No. K821656.
2. **DuoDERM® CGF®**, also distributed by Convatec.
3. **Restore ™**, distributed by Hollister Incorporated, Libertyville, IL, 60048.
4. **Cutinova® hydro**, Distributed by Beirsdorf Incorporated, Norwalk, CT 06856-5529. 510(k) Access No. K905688.

5. **Hydrapad** ™, distributed by Baxter Healthcare Corporation, Pharmaseal Division, Valencia, CA 91355.
6. **Intact**, distributed by C.R. Bard Inc., Murray Hill, NJ 07974.
7. **Comfeel**® Ulcer Care and Pressure Relief Dressings, distributed by Coloplast Inc., Tampa, FL.
8. **Intrasite**, distributed by Smith and Nephew United, Inc., Largo, FL.
9. **Tegasorb**™, distributed by 3M Health Care, St. Paul, MN 55144-1000.

Comparative features between EX-111 and DuoDERM Hydroactive Dressing is presented in Table V in the Product Description section in the main body of the submission (pages 17,18).

(4) **Description of the Device:** The EX-111 is an occlusive wound dressing that belongs to the family of hydrocolloid dressings. The term occlusion refers to the ability of a dressing to prevent desiccation of a wound. It has been known for some time that occlusion of the wound bed promotes reepithelialization. In addition, the dressing acts as a barrier to bacterial infection, and reduces physical trauma at the wound site.

Hydrocolloid dressings are indicated in exudating wounds such as pressure ulcers, venous stasis ulcers, first/second degree burns, and skin donor sites. The hydrocolloid dressing is typically composed of a hydrophobic polymer matrix (such as polyisobutylene) in which hydrophilic, absorbent materials are dispersed.

The presence of these absorbent or absorbent powders, such as cellulose, pectin, gelatin, and carboxymethyl cellulose allow hydrocolloid dressings to absorb the wound exudates, yet remain adherent to the wound and surrounding sites. The proposed device consists of a sterile hydrocolloid pad (the actual size has not been decided, though a typical size is a square with 4 inch sides, with round corners) with a medical grade protective water vapor permeable film/foam/film/adhesive on the outer surface to control moisture vapor transmission and provide a bacterial barrier. The wound contact surface is covered, prior to use, by a non-stick, silicone coated release paper. ***Detailed raw material specifications, including those for the foam layer and the release liner are presented in Appendix I.***

Following the production of the hydrocolloid in rolls at VSC Healthcare, the services of a qualified converter and packager will be used for the addition of the top protective foam containing layer, die cutting to size, and package filling. The dressings will be supplied in sealed blister trays.

Sterilization Information: The product will be sterilized by gamma or electron-beam irradiation following the AAMI guidelines for sterile product release to obtain the final marketable product. A Sterility Assurance Level (SAL) of 10^{-6} will be aimed for. The dosimetric release method will be used for product release. ***The sterilization and product release protocols, along with packaging component specifications are presented in Appendix II.***

(5) **Intended Use of the Device:** The EX-111 device is indicated for the treatment and healing of wounds which typically produce light to moderate amounts of exudates. Pressure sores (decubitus ulcers), venous stasis ulcers, skin graft donor sites, partial thickness wounds, and first/second degree burn wounds can be effectively treated by EX-111.

(6) **Technological Characteristics of the Device: Comparison to the Predicate Device:** On the basis of available product literature and from other published sources, EX 111 is similar in composition to the predicate devices, all hydrocolloid type dressings, as described in item (a) (3) above. ***Comparative features between EX-111 and DuoDERM Hydroactive Dressing is presented in Table V in the Product Description section in the main body of the submission (pages 17,18).***

(7) **Exhibits Pertinent to the Description of the Device:**

The following exhibits have been presented in the main body of the 510(k) submission to better describe the characteristics of the product.

1. Product Samples of EX-111 ***(Exhibit 1).***
2. Proposed Package Label and Insert ***(Exhibit 2, parts A and B).***
3. Predicate Devices Package Labels, Inserts, Product Literature ***(Exhibit 3).***

(b) Performance Data:

The following tests were performed to assess the safety and effectiveness of the device. *The actual exhibits have been presented in the main body of the 510(k) submission, and do not form a part of this summary.*

1. Hemolysis Test ***(Exhibit 4).***
2. Intracutaneous Toxicity Assay ***(Exhibit 5).***

3. Systemic Toxicity Test ***(Exhibit 6)***.
4. Cytotoxicity Test ***(Exhibit 7)***.
5. Sensitization Assay ***(Exhibit 8)***.

All the assay results were negative, which indicates that EX-111 can be expected to perform safely in clinical situations. The above assays were performed based on the "Draft Guidance for the Preparation of a Premarket Notification for a Wound Dressing" published on September 1, 1993 by the Plastic and Reconstructive Surgery Devices Branch, Division of General and Restorative Devices, Office of Device Evaluation. In addition, the water absorbancy of EX-111 and some of the predicate dressings were determined ***(Exhibit 9)***. The data indicated that the absorptive capacity of the EX-111 dressing was comparable to that of the predicate devices. Other comparative features are described in **Table V** on pages 17 and 18

End of 510(k) Summary