December 11, 2024

Wilshire Medical Products
Priscilla Whitehead
Director Quality Assurance/Regulatory Affairs
11420 Mathis Avenue
Dallas, Texas 75234

Re: K936230
Trade/Device Name: DermaAssist™ Petrolatum Gauze, USP, Non-Adhering Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO

Dear Priscilla Whitehead:

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 March 3, 1994. 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
1390 Piccard Drive
Rockville MD 20850

MAR 3 1994

Ms. Priscilla Whitehead
Director Quality Assurance/Regulatory Affairs
Wilshire Medical Products
11420 Mathis Avenue
Dallas, Texas 75234

Re: K936230 - DermAssist™ Petrolatum Gauze, USP, Non-Adhering Wound Dressing
K936234 - DermAssist™ Oil Emulsion Non-Adhering Wound Dressing
Regulatory Class: Unclassified
Dated: December 28, 1993
Received: December 29, 1993

Dear Ms. Whitehead:

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

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

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

4. This 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 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 registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

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If your devices are 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 devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your devices as described. 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 on the labeling for your devices please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) 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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A. Classification Name: 79FRO, Dressing

Common / Usual Name: Non-Adherent Wound Dressing

Proprietary Name: DermAssist™ Petrolatum Gauze, USP

Non-Adhering Wound Dressing

B. Establishment Registration #: 164331

C. Classification: Class I, 21CFR 878~~4060, Dressing~~

D. Performance Standards: None Established

E. Labeling / Promotional

Material & Product Description: Labeling for DermAssist™ Petrolatum Gauze, USP, Non-Adhering Dressing shall consist of a printed pouch & box. Proposed label copy appears on pages 5 & 6. Initial sizes to be marketed are 1/2" X 72", 1" X 8", 1" X 36" & 3" X 9", 3" X 18", 3" X 36"& 6" X 36". Promotional information is shown on pages 7 & 8.

Description / Intended Use: The DermAssist™ Petrolatum Gauze, USP, Non-Adhering Dressing consists of a USP Type I gauze, impregnated with USP White Petrolatum. The dressing has been designed to conform to body contours without sticking to wounds, prevent unnecessary loss of fluid and help seal air leaks. Indications are for first and second degree burns, partial thickness wounds, donor sites, chest tubes, stomas and fistulas, circumcisions and abrasions.

It is supplied sterile in single use metallized polyester mylar pouches. The packaged product will be sterilized by cobalt irradiation with dosimetric release per AAMI guidelines for Method 1, with a sterility assurance level of 10^{-6}. The sterilization validation protocol may be found on pages 15 & 16. Quarterly dose auditing will be performed as recommended by the guidelines. Biocompatibility issues are alleviated due to the 30+ years Petrolatum dressings have been in the market place.

F. Substantial Equivalence: This product is similar in design, composition and function to the Inman Medical Corporation Petrolatum Dressing, 510(k) # K921289 approved November 1992. Labeling claims are identical. A copy of the IMC 510(k) approval letter & product labeling may found on pages 10 - 13.

G. Safety & Effectiveness Summary: The DermAssist™ Petrolatum Gauze, USP, Non-Adhering Dressing consists of a USP Type I gauze, impregnated with USP White Petrolatum. The dressing has been designed to conform to body contours without sticking to wounds, prevent unnecessary loss of fluid and help seal air leaks. Indications are for first and second degree burns, partial thickness wounds, donor sites, chest tubes, stomas and fistulas, circumcisions and abrasions.

It is supplied sterile in single use metallized polyester mylar pouches. The packaged product will be sterilized by cobalt irradiation with dosimetric release per AAMI guidelines for Method 1, with a sterility assurance level of 10^{-6}. Quarterly dose auditing will be performed as recommended by the guidelines. Biocompatability issues are alleviated due to the 30+ years this type of dressing has been marketed

This product is similar in design, composition and function to the Inman Medical Corporation Petrolatum Dressing, 510(k) # K921289 approved November 1992. Labeling claims are identical.

WILSHIRE MEDICAL PRODUCTS

11420 Mathis Avenue, Dallas, Texas 75234 • (214) 869-1727 • (800) 234-8132 • FAX (214) 869-0649

MAR 3 1994

510(k)# K936230
DermAssist™ Petrolatum Gauze, USP

Safety & Effectiveness Summary: DermAssist™ Petrolatum Gauze, USP

Classification Name: 79FRO,Dressing

Common / Usual Name: Non-Adhering Dressing

Submitted By:

Wilshire Medical Products
11420 Mathis Avenue
Dallas, TX 75234
(214) 869-1727

Contact: Priscilla Whitehead, Director QA/RA

Prepared: February 28, 1994

The DermAssist™ Petrolatum Gauze, USP, Non-Adhering Dressing consists of a USP Type I gauze, impregnated with USP White Petrolatum. The dressing has been designed to conform to body contours without sticking to wounds, prevent unnecessary loss of fluid and help seal air leaks. Indications are for first and second degree burns, partial thickness wounds, donor sites, chest tubes, stomas and fistulas, circumcisions and abrasions.

It is supplied sterile in single use metallized polyester mylar pouches. The packaged product will be sterilized by cobalt irradiation with dosimetric release per AAMI guidelines for Method 1, with a sterility assurance level of 10^{-6}. Quarterly dose auditing will be performed as recommended by the guidelines. Biocompatibility issues are alleviated due to experience of years non-adhering dressings have in the market place.

This product is similar in design, composition and function to the Inman Medical Corporation Petrolatum Dressing, 510(k) # K921291approved January 1993. Labeling claims are identical.