January 10, 2025

PolyMedica Wound Care Company
Julie Chaffee
Manager of Quality and Regulatory Affairs
581 Conference Place
Golden, Colorado 80401

Re: K964701
Trade/Device Name: MITRAFLEX® Pigmented Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO

Dear Julie Chaffee:

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 February 7, 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

Ms. Julie Chaffee
Manager of Quality and Regulatory Affairs
PolyMedic Wound Care Company
581 Conference Place
Golden, Colorado 80401

FEB - 7 1997

Re: K964701
Trade Name: MITRAFLEX® Pigmented Wound Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: November 22, 1996
Received: November 25, 1996

Dear Ms. Chaffee:

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, (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

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K964701

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: Unassigned
PolyMedica Industries, Inc.

Device Name: MITRAFLEX® Pigmented Wound Dressings

Indications for Use:

MITRAFLEX Pigmented Wound Dressings provide a degree of absorption and breathability. They are intended for use in the management of the following:

Venous stasis ulcers	Partial-thickness wounds
Diabetic ulcers	Superficial burns
Pressure sores	Abrasions and lacerations
Donor sites	Full-thickness wounds
Blisters	Skin tears
Incisions	Dermal lesions
Severe sunburn	Minor chemical burns
Poison Ivy	Thermal burns

Dermabrasions and other dermatologic procedures
Facelifts and other plastic surgery procedures (e.g. laser resurfacing)

(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 K964701

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

K964701 FEB -7 1997

510(k) Summary

Proprietary Name: MITRAFLEX® Pigmented Wound Dressing

Common Name: Dressing

Classification: Unclassified

Submitter's Details: PolyMedica Industries, Inc.
581 Conference Place
Golden, CO 80401
Tel: (303)271-0300
FAX: (303)271-0397
Contacts: Andrew M. Reed, Ph.D., Julie Chaffee

Description:

MITRAFLEX Pigmented Wound Dressings are sterile, absorptive dressings.

MITRAFLEX combines the moist wound environment properties of film dressings with the absorptive qualities of traditional therapies in a structure which is both adhesive and conformable.

MITRAFLEX dressings are constructed of three layers, each specifically engineered to give MITRAFLEX its unique blend of "ease of use" features while providing a microenvironment conducive to moist wound healing.

The wound contact surface of MITRAFLEX is a porous adhesive which facilitates ease of application to the wound site. A second layer consisting of a microporous polyurethane membrane absorbs and acts as a reservoir for wound exudate. This layer is also moisture vapor permeable which facilitates the reduction of exudate while maintaining a moist environment to promote optimal wound repair. MITRAFLEX is impermeable to microorganisms and liquids.

MITRAFLEX Pigmented Wound Dressings are intended for use in the management of:

Venous stasis ulcers	Partial-thickness wounds
Diabetic ulcers	Superficial burns
Pressure sores	Abrasions and lacerations
Donor sites	Full-thickness wounds
Blisters	Skin tears
Incisions	Dermal lesions
Severe sunburn	Minor chemical burns
Poison Ivy	Thermal burns

Dermabrasions and other dermatologic procedures
Facelifts and other plastic surgery procedures (e.g. laser resurfacing)

MITRAFLEX Pigmented Wound Dressings are substantially equivalent to MITRAFLEX Wound Dressings, Wet-Stick, and MITRAFLEX Wound Dressings. These devices are all self-adhesive wound dressings which provide a degree of absorption and breathability. They are all intended for use in the management of a wide variety of dermal lesions and injuries.

MITRAFLEX Pigmented Wound Dressings have been shown in laboratory tests to be nontoxic, nonirritating, and nonsensitizing.