

OCT 24 1997

**510(k) Summary**

**Proprietary Name:** SPYROFLEX® Pigmented Wound Dressing For OTC Use

**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:**

SPYROFLEX® is a sterile, conformable, absorptive dressing.

SPYROFLEX dressings consists of two layers, each specifically engineered to give SPYROFLEX its unique blend of "ease of use" features while maintaining a protective moist healing environment.

The wound contact surface of SPYROFLEX is a porous, non-toxic adhesive which facilitates ease of application to the wound site. A second layer consisting of a microporous polyurethane membrane acts as a reservoir for wound exudate. The outer layer performs as a barrier to bacteria, dirt, and liquids.

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

- Abrasions
- Blisters
- Burns (sun burns, carpet burns, friction burns, minor chemical and heat burns)
- Cuts
- Lacerations
- Poison Ivy
- Rash
- Scrapes

SPYROFLEX Pigmented Wound Dressings For OTC Use are substantially equivalent to SPYROFLEX Pigmented Wound Dressings. These devices are self-adhesive wound dressings which provide a degree of absorption and breathability. They are intended for use in the management of a wide variety of wounds and injuries. These dressings have been shown in laboratory tests to be nontoxic, nonirritating, and nonsensitizing.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 24 1997

Ms. Julie Chaffee  
Manager, Regulatory and Quality Assurance  
Innovative Technologies (US) Inc.  
581 Conference Place  
Golden, Colorado 80401

Re: K964398  
SPYROFLEX® Pigmented Wound Dressings for OTC Use  
Regulatory Class: Unclassified  
Product Code: MGP  
Dated: October 3, 1997  
Received: October 6, 1997

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

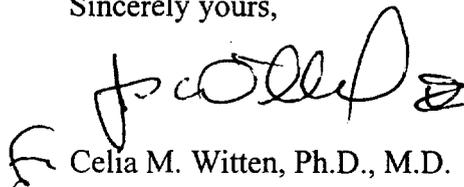
807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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 Division of Small Manufacturers Assistance at the number 800 638-2041 or 301-443-6597 or 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

**PREMARKET NOTIFICATION**

**INDICATIONS FOR USE STATEMENT**

510(k) Number: K964398  
~~Unassigned~~  
PolyMedica Industries, Inc.

Device Name: **SPYROFLEX® Pigmented Wound Dressings For OTC Use**

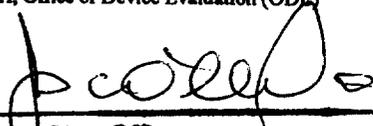
Indications for Use:

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

- Abrasions
- Blisters
- Burns (sun burns, carpet burns, friction burns, minor chemical and heat burns)
- Cuts
- Lacerations
- Poison Ivy
- Rash
- Scrapes

**(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 K964398

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)