

K974520

FEB - 6 1998

510(k) SPYROFLEX® Foam Island Wound Dressing
Innovative Technologies (US) Inc.

510(k) Summary

Prescription Use

Proprietary Name: SPYROFLEX® Foam Island Wound Dressing
Common Name: Dressing
Classification: Unclassified
Submitter's Details: Innovative Technologies (US), Inc.
581 Conference Place
Golden, CO 80401
Tel: (303)271-0340
FAX: (303)271-0397
Contacts: Andrew M. Reed, Ph.D., Julie Chaffee

Description:

SPYROFLEX Foam Island Wound Dressings are sterile, absorptive dressings.

SPYROFLEX 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.

The wound contact surface of SPYROFLEX is an absorptive foam island dressing. A second layer consisting of a microporous polyurethane self adhesive membrane facilitates the ease of application to the wound site. This layer is moisture vapor permeable and impermeable to microorganisms and liquids.

SPYROFLEX Foam Island 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

SPYROFLEX Foam Island Wound Dressings are substantially equivalent to SPYROFLEX Pigmented Wound Dressings, and Tielle Hydropolymer Dressings. These devices are 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.

SPYROFLEX Foam Island Wound Dressings have been shown in laboratory tests to be nontoxic, nonirritating, and nonsensitizing.

510(k) SPYROFLEX® Foam Island Wound Dressing
Innovative Technologies (US) Inc.

510(k) Summary

Over-The-Counter Use

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

- Abrasions
- Superficial Blisters
- Minor Burns
- Superficial Cuts
- Superficial Lacerations
- Superficial Scrapes
- Minor Rash

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

FEB - 6 1998

Re: K974520
SPYROFLEX® Foam Island Wound Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: December 1, 1997
Received: December 2, 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 (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

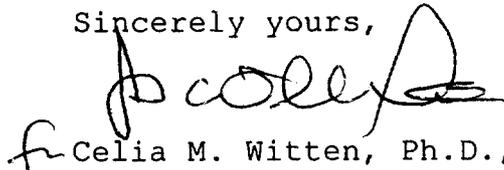
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

Page 2 - Ms. Julie Chaffee

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 or (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

510(k) SPYROFLEX® Foam Island Wound Dressing
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PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(k) Number: K974520
Innovative Technologies (US), Inc.

Device Name: SPYROFLEX® Foam Island Wound Dressing

Indications for Use:

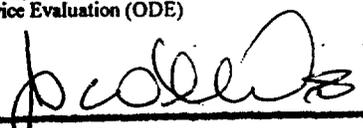
- Prescription Use -

SPYROFLEX Foam Island 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
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Poison Ivy	Thermal burns

(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 K974520

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

510(k) SPYROFLEX® Foam Island Wound Dressing
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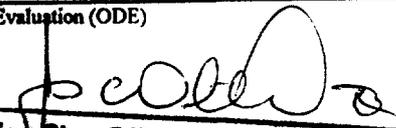
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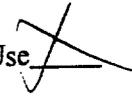


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