K980673

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

MAY 21 1998

510(k) Summary
K980673

Proprietary Name: Spyrosorb® 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:

Spyrosorb Foam Island Wound Dressings are sterile, absorptive dressings.

Spyrosorb 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 Spyrosorb 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. The outermost layer acts as a barrier to exogenous moisture and bacteria while allowing permeability to moisture vapor and oxygen.

Spyrosorb Foam Island Wound Dressings are intended for use in the management of partial and full thickness wounds under the direction of a health care professional such as:

- Venous stasis ulcers
- Diabetic ulcers
- Pressure sores
- Donor sites
- Burns, Minor and Chemical
- Abrasions and lacerations
- Incisions

Over the Counter usages include superficial abrasions, scrapes, cuts, and lacerations, as well as minor burns.

Spyrosorb Foam Island Wound Dressings are substantially equivalent to Mitraflex 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 wounds.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAY 21 1998

Re: K980673
Trade Name: SPYROSORB® Foam Island Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: February 19, 1998
Received: February 20, 1998

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).

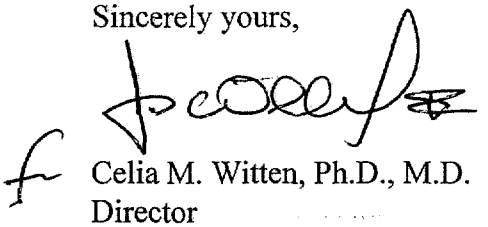
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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 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) Spyrosorb® Foam Island Wound Dressing
Innovative Technologies (US) Inc.

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(k) Number: K980673
Innovative Technologies (US), Inc.

Device Name: Spyrosorb® Foam Island Wound Dressing

Indications for Use:

Spyrosorb Foam Island Wound Dressings provide a degree of absorption and breathability. They are intended for use in the management of partial and full thickness wounds.

The following indications for use are for Prescription Use or under the direction of a health care professional:

- Venous stasis ulcers
- Diabetic ulcers
- Pressure sores
- Donor sites
- Burns, Minor and Chemical
- Abrasions and lacerations
- Incisions

The following indications for use are for Over The Counter Use:

- Superficial Abrasions, Scrapes, Cuts, and Lacerations
- Minor 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 K980673

Prescription Use ✓ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)