

3/19/99

K990042



101 Technology Drive ♦ Bethlehem, PA 18015  
Phone: (610) 974-8801 FAX: (610) 974-8831  
Toll Free: 1-800-25-SILON (257-4566)  
<http://www.silon.com>

### XIII. 510(k) SUMMARY

#### **SILON® DUAL-DRESS™**

#### PRODUCT DESCRIPTION

Silon® Dual-Dress™ is a single dressing with two different sides. One side consists of an open-celled hydrophilic foam. The other side consists of a non-adherent semi-occlusive film. The semi-occlusive film is perforated to allow wound exude to wick away from the wound.

With the foam side of the dressing down against the wound, the product provides an adhesive surface for difficult fixation conditions. With the film side down, the dressing provides a non-adherent covering for fragile and sensitive wounds. One side of the dressing is clearly marked with the product name and the words "Foam on Other Side" printed with a biocompatible ink.

#### INDICATIONS FOR USE

For the management of partial and full thickness wounds including the following:

- Second Degree Burns
- Skin Graft Donor Sites
- Autograft Sites
- Abrasions
- Lacerations
- Stage II – III Chronic Wounds (Venous Stasis, Decubitus & Diabetic)
- Skin Tears

#### Contraindications (either side down):

- Third Degree Burns

#### SUBSTANTIAL EQUIVALENCE

Bio Med Sciences claims substantial equivalency for Silon® Dual-Dress™ to the following devices:

1. Silon Transparent Wound Dressings  
(Bio Med Sciences, Inc. 510K #s K912032 & K923150)
2. Epitec® Dressing  
(Rynel Ltd, Inc. 510K #K971337)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 19 1999

Mr. Mark E. Dillon  
President  
BioMed Sciences, Inc.  
101 Technology Drive  
Bethlehem, Pennsylvania 18015

Re: K990042  
Trade Name: Silon Dual-Dress  
Regulatory Class: Unclassified  
Product Code: MGP  
Dated: January 4, 1999  
Received: January 6, 1999

Dear Mr. Dillon:

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).

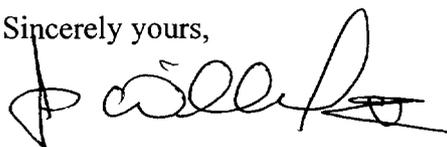
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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) NUMBER (IF KNOWN): K990042

DEVICE NAME: Silon Dual-Dress

INDICATIONS FOR USE:

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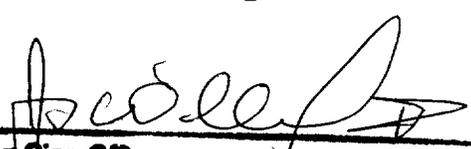
- Second Degree Burns
- Skin Graft Donor Sites
- Autograft Sites
- Abrasions
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- Skin Tears

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K990042