



AUG 6 1998

K982036

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XIII. 510(k) SUMMARY

SILON® SCAR STRIPS

PRODUCT DESCRIPTION

The Applicant presently markets Silon-SES® Silicone Elastomer Sheeting for the management of hypertrophic scars and keloids. The new product does not introduce any new concepts in silicone scar management products. Silon-SES is presently labeled for sale by or on the order of a physician. The Applicant hereby intends to remove this restriction and offer the product directly to consumers “over-the-counter.”

INDICATIONS FOR USE

Silon Scar Strips are indicated for the management of hypertrophic scars and keloids. Consistent use of Silon Scar Strips can reduce hypertrophic scarring and keloid formation resulting from surgical or traumatic injury of the skin.

Silon Scar Strips may be useful as a prophylaxis after surgical or traumatic dermal injury to aid in the prevention of hypertrophic scars and keloids.

SUBSTANTIAL EQUIVALENCE

The new product is substantially equivalent to the existing Silon-SES product (510(k) No. K932214), as well as Rejuveness (510(k) No. K974380) by Rich Mark International – which offers their product for sale “over-the-counter”.

BIOCOMPATIBILITY SUMMARY

The Silon-SES material passes the Tripartite Biocompatibility Guidance for Medical Devices as prepared by the Toxicology Sub-group of the Tripartite Sub-Committee on Medical Devices (September 1986) as related to external devices contacting intact surfaces for long durations. Each of the materials used in the new device have long histories of use in the medical field, and are utilized in each of the other woundcare and scar management products presently manufactured and marketed by Bio Med Sciences. All tests were performed by an FDA registered independent testing company. The data can be summarized as follows:

Test	Results
Kligman Maximization	Non-sensitizing (0% sensitization)
Primary Dermal Irritation	Non-irritant (PDII = 0)
Agarose Diffusion Cytotoxicity	No cytopathic effects (grade 0)
Acute Systemic Cytotoxicity	Passes



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K982036
Trade Name: Silon Scar Strips
Regulatory Class: Unclassified
Product Code: MDA
Dated: June 9, 1998
Received: June 10, 1998

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 (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 (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, 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.

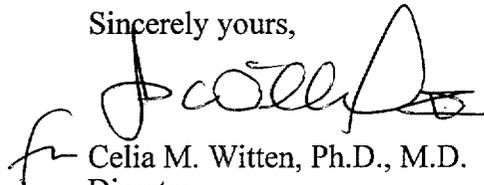
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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

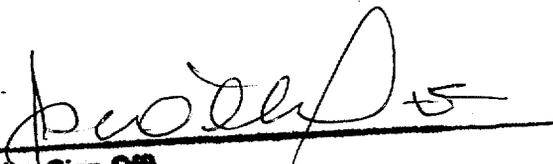
Enclosure

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 14982036

Over-the-Counter Use