DEC 7 1998

FDA/CDRH/ODE/DMC

24 Jun 98 10 5 05

K981065

Bio Med Sciences, Inc.
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

Summary
510 (k) Premarket Notification

CONTACT PERSON

Mark E. Dillon, President, Bio Med Sciences, Inc.

PRODUCT NAME

Silon® Topomat™ Corneal Topography Image Enhancement Device

PRODUCT DESCRIPTION

The Silon Topomat device provides a convenient method of imaging the surface of the cornea with existing corneal topography apparatuses while avoiding the use of dyes and wetting agents.

The Silon Topomat device consists of a hydrophobic silicone-based membrane. It can accurately contour to irregular surfaces, closely following even minute topographical features. The membrane is fixed within two couplings as to provide a rigid ring structure in the form of a "drum-head" of approximately 13 millimeters in diameter. The ring has a gripping tab on one edge to facilitate handling and serve as an orientation reference. The membrane is applied against the surface of the cornea, and an accurate topographic image is obtained directly from the distal surface of the membrane using videokeratographic or rasterstereographic imaging techniques.

PRODUCT EQUIVALENCY

Bio Med Sciences claims substantial equivalency for Silon Topomat to the following devices:

1. **Silon® Transparent Wound Dressings (K912032 & K923150)**
   Bio Med Sciences, Inc.
   101 Technology Drive
   Bethlehem, PA 18015 USA

   Silon interpenetrating polymer network of polydimethylsiloxane and polytetrafluoroethylene in membrane form used on de-epithelialized dermal tissue.

2. **SilSoft® Aphakic Extended-Wear Contact Lens**
   Bausch & Lomb
   One Bausch & Lomb Place
   P.O. Box 450
   Rochester, NY 14692

® Registered Trademark, Bio Med Sciences, Inc.

Soft contact lens made from Elastofilcon A™ polydimethylsiloxane from Dow Corning corporation. Used in direct contact with the human eye.

3. **Fluorescein Dye**

Akorn, Inc.
100 Akorn Drive
Abita Springs, LA 70420

Used as an image enhancement dye for corneal topographic mapping.

BIOCOMPATIBILITY SUMMARY

The Silon membrane 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 breached surfaces for short durations. The tests were performed by an FDA registered independent testing company (Toxicon Corporation of Woburn, MA). The data can be summarized as follows:

Test	Results	Toxicon Reference
Kligman Maximization	Non-sensitizing (0% sensitization)	91G-0388
Primary Dermal Irritation	Non-irritant (PDII = 0)	91G-0387
Hemolysis	Non-hemolytic (2.0 %)	90G-0670
Agarose Overlay Cytotoxicity	No cytopathic effects (grade 0)	90G-0669
MEM Cytotoxicity	Non-cytotoxic (grade 0)	90G-0668

Bio Med Sciences has taken the following position relative to the use of the proposed materials:

1) The Silon membrane material is the corneal contacting surface of the device, and therefore is the material of interest with respect to biocompatibility.
2) In all biocompatibility tests conducted to date, the Silon membrane has never induced a negative biological response.
3) The Silon membrane is presently used for woundcare applications wherein it is in direct contact with de-epithelialized tissue for up to 10 days.
4) The device is only used intermittently for short periods, and therefore is not subject to more rigorous biocompatibility requirements.
5) Although not in direct contact with the patient, the polyethylene ring and the opacifying agent are known to be generally regarded as safe and are both sterilizable by the EtO method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 7 1998

Mr. Mark E. Dillon
President
Bio Med Science, Inc.
101 Technology Drive
Bethlehem, PA 18015

Re: K981665
Trade Name: Silcon® Topomat ™ Corneal Topography Image Enhancement Device
Regulatory Class: I
Product Code: 86 MMQ
Dated: November 13, 1998
Received: November 18, 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 requirements, 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.

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) 594-4613. 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. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K981665

Device Name:

Silon® Topomat™ Corneal Topography Image Enhancement Device

Indications For Use:

For the measurement of the topographical surface of the cornea using rasterstereographic imaging techniques.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K981665

Prescription Use ✓
(Per 21 CFR 801.109)

® Registered Trademark, Bio Med Sciences, Inc.