

K982688

OCT 13 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

SPECTRUM DESIGNS PRE-FORM CONTOUR SILICONE CARVING BLOCK IMPLANT

510K SUMMARY

1. Submitter's Data

Spectrum Designs Inc.
6387 B. Rose Lane
Carpinteria, CA 93117

Contact Person: Jim Dishman
Telephone: (805) 684 -7678
Date Prepared: July 22, 1998

2. Device Name, Classification

Name: Spectrum Designs Pre-Form Contour Silicone Carving Block
FDA Classification: Class II
FDA Code: MIB

3. Identification of Substantially Equivalent Devices

Spectrum Designs Silicone Block Implant
Spectrum Designs Pectoral Implant
Silimed Elastomer, Silicone Block , SILIMED Calf Implant

4. Device Description

The Spectrum Designs Pre-Form Contour Silicone Carving Block Implant is fabricated from solid silicone elastomer and has an inherent, pre-formed, rounded shape.

5. Indications for Use

The Spectrum Designs Pre-Form Contour Carving Block is a pre-formed solid silicone block to be used where a shaped, cut-to-fit implant is desired.

6. Contraindications for Use

Contraindications for routine aesthetic surgery include the presence of infection anywhere in the body and in particular, in the region in which the device will be implanted.

7. Warnings, Precautions

Possible complications include:

- Displacement of the implant may occur, especially from dissection of too large a pocket.
- Errors in positioning the implant may result in patient dissatisfaction
- Tissue necrosis may result in extrusion of the implant. This can occur as a result of such factors as the pocket created being too small, use of too large an implant, or when soft tissues are inadequate to maintain coverage over the prosthesis
- Resorption of the underlying bone may occur with use of the implant.
- Fibrous tissue encapsulation can occur around any implant, with subsequent increased firmness, possible displacement, and/or pains.
- Complications from this or any similar surgery may include infection, neural damage, hematoma, poor wound healing, patient intolerance to foreign body implantation, and other similar complications.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 1998

Mr. Jim Dishman
President
Spectrum Designs, Inc.
6387 B Rose Lane
Carpinteria, California 93013

Re: K982688
Trade Name: Spectrum Designs Pre-Form Contour Silicone
Carving Block
Regulatory Class: Unclassified
Product Code: MIB
Dated: July 22, 1998
Received: August 03, 1998

Dear Mr. Dishman:

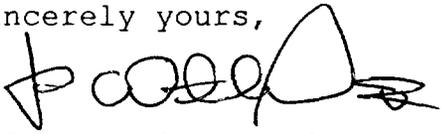
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,


f 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

