SUMMARY OF SAFETY AND EFFECTIVENESS

K980139

SPECTRUM DESIGNS INC. PROFILE MALAR IMPLANT
510K SUMMARY

MAR - 3 1998

1. **Submitter's Data**

Spectrum Designs Inc.
5921 C Matthews Street
Goleta, CA 93117

Contact Person: Jim Dishman
Telephone: 805 681 4899
Date Prepared: December 30, 1997

2. **Device Name, Classification**

Name: Spectrum Designs Profile Malar Implant
FDA Classification: Class II, Implant, Malar, Classification 79LZK

3. **Identification of Substantially Equivalent Devices**

Spectrum Designs Silhouette Malar Implant

4. **Device Description**

Spectrum Designs Profile Malar Implant is manufactured from solid silicone elastomer. The implant is implanted in a pocket created by the surgeon in the malar-zygomatic region of the facial skeleton to augment the existing facial structure.

5. **Indications for Use**

The Spectrum Designs Profile Malar Implant is a silicone facial implant, designed to augment or reconstruct the malar region of the face.

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 would healing, patient intolerance to foreign body implantation, and other similar complications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jim Dishman
President
Spectrum Designs, Incorporated
5921 C. Matthews Street
Goleta, California 93117

MAR - 3 1998

Re: K980139, K980140 & K980141
Trade Name: Spectrum Designs Profile Malar Implant
Spectrum Designs Medial Malar Implant and
Spectrum Designs Projection Malar Implant
Regulatory Class: II
Product Code: LZK
Dated: December 30, 1997
Received: January 15, 1998

Dear Mr. Dishman:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosures) 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification

submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,

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

Enclosures

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire 510(k) submission must support and agree with the "indications for use" statement.
*For a new submission, do NOT fill in the 510(k) number blank.

INDICATIONS FOR USE

Applicant: Spectrum Designs, Inc.

510(k) Number (if known): K980139 *

Device Name: Spectrum Designs Profile Malar Implant

Indications For Use

The Spectrum Designs Profile Malar Implant is intended to augment or reconstruct the malar region of the face.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980139

Prescription Use X or Over-the counter ____
Per 21 CFR 801.109