K982763

SEP 30 1998

SEARE BIOMEDICAL CORPORATION

510(k) Summary

Contact Information: Seare Biomedical Corporation
3190 Chula Vista Circle
Salt Lake City, Utah 84121
Telephone: 1(801) 355-5533
Facsimile: 1(801) 942-1999

Trade Name: Seare Biomedical Malar Implants

Common Name: Silicone Elastomer Malar Implants

Classification Name: Implant, Malar

Substantial Equivalence: The Seare Biomedical Malar Implant configurations are substantially equivalent in material, function, performance, and design to the Allied Biomedical Malar Implants manufactured and marketed by Allied Biomedical.

Device Description: Seare Biomedical Malar implants are crescent shaped concave convex silicone elastomer rubber implants made from specially formulated silicone elastomers designed for implantation. They are manufactured in pairs with a mirror image left and right. Surface characteristics will vary from smooth to varying degrees of texturing and porosity. Seare Biomedical Malar Implants are intended to be used to augment or reconstruct the maxilla for cosmetic or reconstructive surgery. The Seare Biomedical Malar Implants will be produced using standard manufacturing molding techniques. The Seare Biomedical Malars will be available in many sizes and styles, all of which are very similar - differing only by a few millimeters in length and projection. The Seare Biomedical Malar Implants will be provided sterile and nonsterile.

Indications For Use: Seare Biomedical Malar Implants are intended to be used to augment or reconstruct the maxilla for cosmetic or reconstructive surgery.

Predicate Devices: The Seare Biomedical Malar Implant configurations are substantially equivalent in material, function, performance, and design to the Allied Biomedical Malar Implants manufactured and marketed by Allied Biomedical. The products have identical indications for use and are offered in the same exact size and options.

Clinical Tests: None

Adverse S&E Information: None

William J. Seare, Jr. M.D.
President & C.E.O.

8/4/98
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 1998

William J. Seare, M.D.
President & C.E.O.
Seare Biomedical Corporation
3190 Chula Vista Circle
Salt Lake City, Utah 84121

Re: K982763
Trade Name: Seare Biomedical Malar Implants
Regulatory Class: II
Product Code: LZK
Dated: August 04, 1998
Received: August 06, 1998

Dear Dr. Seare:

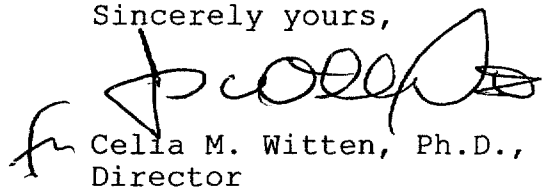
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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): K982763

Device Name: Seare Biomedical Malar Implants

Indications For Use:

Seare Biomedical Malar Implants are intended to be used to augment or reconstruct the maxilla for cosmetic or reconstructive surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices K982763
510(k) Number

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)