



K982762

# SEARE BIOMEDICAL CORPORATION

SEP 30 1998

## 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 Pectoralis Implants  
**Common Name:** Silicone Elastomer Pectoralis Implants  
**Classification Name:** Implant, Muscle, Pectoralis

**Substantial Equivalence:** The Seare Biomedical Pectoralis Implant configurations are substantially equivalent in material, function, performance, and design to the Allied Biomedical Pectoralis Implants manufactured and marketed by Allied Biomedical and Hanson Medical Inc. (

**Device Description:** Seare Biomedical Pectoralis implants are essentially large concave convex oval shaped silicone elastomer rubber implant (carving blocks) made from specially formulated silicone elastomers designed for implantation. They are provided in two (2) orientations for each of three (3) styles, with a mirror image left or right availability. Surface characteristics will vary from smooth to varying degrees of texturing and porosity. Seare Biomedical Pectoralis Implants / silicone carving blocks are intended to be used for augmenting the chest by placing the implant in the submuscular space via a trans-axillary incision. They can also be used to reconstruct the pectoralis depression of Poland's Syndrome (Congenitally Absent Pectoralis Muscle). The Seare Biomedical Pectoralis implants will be available in many sizes and styles, all of which are very similar - differing in length and projection. The length of these implants varies from 11.5cm to 20cm. The height varies from 9cm to 18cm and the thickness at the apex varies 1cm to 3.5cm. The Seare Biomedical Pectoralis Implants will be provided sterile and nonsterile.

**Indications For Use:** Seare Biomedical Pectoralis Implants / silicone carving blocks are intended to be used for augmenting the chest by placing the implant in the submuscular space via a trans-axillary incision. They can also be used to reconstruct the pectoralis depression of Poland's Syndrome (Congenitally Absent Pectoralis Muscle).

**Predicate Devices:** The Seare Biomedical Pectoralis Implant configurations are substantially equivalent in material, function, performance, and design to the Allied Biomedical Pectoralis Implants manufactured and marketed by Allied Biomedical and Hanson Medical Inc. The products have identical indications for use and are offered in the same sizes and options.

**Clinical Tests:** None

**Adverse S&E Information:** None

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

8/4/98  
Date



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: K982762  
Trade Name: Seare Biomedical Pectoralis Implants  
Regulatory Class: Unclassified  
Product Code: MIC  
Dated: August 04, 1998  
Received: August 06, 1998

Dear Dr. Seare:

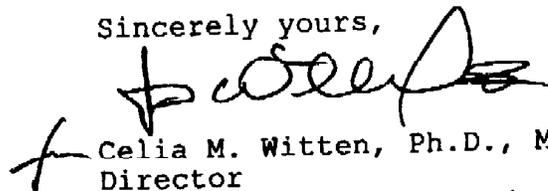
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K98 2762

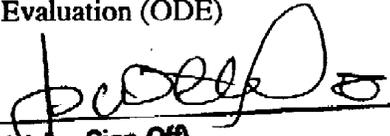
Device Name: Seare Biomedical Pectoralis Implants

Indications For Use:

Seare Biomedical Pectoralis Implants / silicone carving blocks are intended to be used for augmenting the chest by placing the implant in the submuscular space via a trans-axillary incision. They can also be used to reconstruct the pectoralis depression of Poland's Syndrome (Congenitally Absent Pectoralis Muscle).

(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  
510(k) Number K982762

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use