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 availablity. 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

JAN 1 0 2017

Re: K982762
Trade/Device Name: Seare Biomedical Pectoralis Implants
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: II
Product Code: MIC
Dated: August 4, 1998
Received: August 6, 1998

Dear Mr. Seare:

This letter corrects our substantially equivalent letter of September 30, 1998.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): K982762

Device Name: Seare Biomedical Pectoralis Implants

Indications For Use:

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(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 X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)