

SEP 30 1998



K983043

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 Silicone Blocks

Common Name: Silicone Elastomer Carving Blocks

Classification Name: Elastomer, Silicone Block

Substantial Equivalence: The Seare Biomedical Silicone Block configurations are substantially equivalent in material, function, performance, and design to the Allied Biomedical Silicone Blocks manufactured and marketed by Allied Biomedical Corporation and Hanson Medical Inc.

Device Description: Seare Biomedical Silicone Blocks are made from specially formulated silicone elastomers designed for implantation, LSR soft implant grade silicone elastomer. The intended use of the Seare Biomedical silicone block is for carving a finished device by the surgeon for his or her own custom use. The square or rectangular blocks are designed for carving flatter devices for use in bone onlay for correction of surface defects resulting from skeletal anomalies such as depressions secondary to trauma or cancer resection. The curved blocks are generally used for carving curved devices such as malar and chin implants. The Seare Biomedical Silicone Blocks will be provided sterile and nonsterile. The appearance is described as clear to slightly opaque. Pigments will optionally be added such as Iron Oxide and Titanium Oxide, to create opacity to light and Radiographic exam.

Indications For Use: Seare Biomedical Silicone Blocks are intended for use in the cosmetic correction of soft tissue deformities, and is contoured at the surgeon's discretion to create a custom implant to aid in the reconstruction process. The contour carving blocks lend themselves to carving chin implants and malar implants.

Predicate Devices: The Seare Biomedical Silicone Block configurations are substantially equivalent in material, function, performance, and design to the Allied Biomedical Silicone Blocks manufactured and marketed by Allied Biomedical and Hanson Medical Inc. The products have identical indications for use and are offered in the same basic 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.

August 27, 1998
Date



SEP 30 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983043
Trade Name: Seare Biomedical Silicone Block
Regulatory Class: Unclassified
Product Code: MIC
Dated: August 27, 1998
Received: August 31, 1998

Dear Dr. Seare:

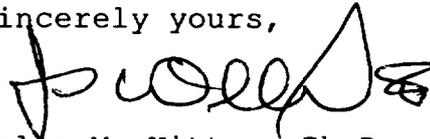
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



Cella 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): K983043

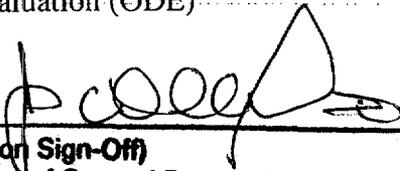
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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983043

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use