

**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 Tissue Expanders

Common Name: Silicone Tissue Expanders

Classification Name: Expander, Skin, Inflatable

Substantial Equivalence: The Seare Biomedical Silicone Tissue Expander configurations are substantially equivalent in material, function, performance, and design to the Silicone Tissue Expanders manufactured and marketed by Specialty Surgical Products, Inc. and McGhan Medical Corporation. The products have comparable indications for use and are offered in the same exact sizes and basic options.

Device Description: Seare Biomedical Silicone Tissue Expanders are intended for temporary subcutaneous implantation to develop surgical flaps and additional tissue coverage. The tissue expander assemblies are designed to be implanted completely under the skin, and filled externally via a syringe. All tissue expanders require periodic, incremental inflation with sterile saline for injection, until the desired amount of tissue is developed. The Seare Biomedical Silicone Tissue Expanders are constructed as a unit from silicone elastomer and consist of an expansion envelope with a smooth surface, a silicone connection tube, and a remote injection site. The expanders are available in a wide range of styles and sizes to meet diverse surgical needs.

Indications For Use: Seare Biomedical Silicone Tissue Expanders are intended for temporary subcutaneous implantation to develop surgical flaps and additional tissue coverage required in a wide variety of applications, particularly to aid in reconstruction following mastectomy, to aid in the treatment of underdeveloped breasts, and to aid in the treatment of soft tissue deformities.

Predicate Devices: The Seare Biomedical Silicone Tissue Expander configurations are substantially equivalent to the predicate device Silicone Tissue Expanders manufactured and marketed by Specialty Surgical Products, Inc. and McGhan Medical Corporation.

Clinical Tests: None

Adverse S&E Information: None

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

10/13/99
Date



DEC 11 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

William J. Seare, Jr., M.D.
President and Chief Executive Officer
Seare Biomedical Corporation
3190 Chula Vista Circle
Salt Lake City, Utah, 84121

Re: K983792
Trade Name: Seare Biomedical Silicone Tissue Expander
Regulatory Class: Unclassified
Product Code: LCJ
Dated: October 13, 1998
Received: October 27, 1998

Dear Dr. Seare:

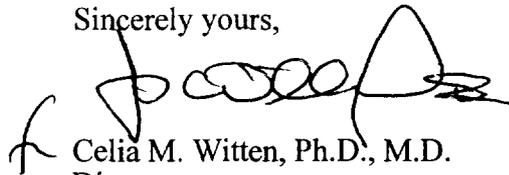
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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): K983792

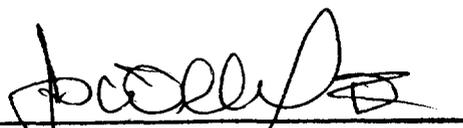
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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983792

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use