K983041

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 Silicone Sheeting

Common Name: Silicone Elastomer Sheeting

Classification Name: Elastomer, Silicone Block

Substantial Equivalence: The Seare Biomedical Silicone Sheeting configurations are substantially equivalent in material, function, performance, and design to the Silicone Elastomer Sheeting manufactured and marketed by Dow Corning and Bentec Medical.

Device Description: Seare Biomedical Silicone Sheeting is made from specially formulated silicone elastomers designed for implantation, LSR soft implant grade silicone elastomer. Seare Biomedical Silicone Elastomer Sheeting is a flexible, translucent, medical grade silicone elastomer sheeting material designed for a variety of implant applications. It is available in polyester mesh reinforced and nonreinforced in a variety of thicknesses. Surface characteristics will vary from smooth to varying degrees of texturing and porosity. The Silicone Sheeting may be readily trimmed with a knife or scissors. This trimmable feature allows the surgeon to custom fabricate, at surgery, an implantable prosthesis for a specific surgical indication.

Indications For Use: Seare Biomedical Silicone sheeting is intended for a variety of uses. For short term application the indications for use are: nasal splinting; wound dressings; management of hypentrophic or keloid scarring; to prevent soft tissue fibrosis or bony ankylosis following surgical correction of trismus; temporary joint spacers; and laboratory uses.

For long-term application the indications for use are: nasal septal repair; orbital floor reconstruction; tympanic membrane repair; dialysis shunt anchoring; duramater repair; staged repair of omphalocele; for lengthening extra ocular muscles in select cases of strabismus; as a protective sheathing to help facilitate neural regeneration and tendon anastomosis; as a protective sheathing to help facilitate osteogenesis; guided tissue regeneration between teeth and gingival margin, or external ear canal for example; subcutaneous tissue augmentation; subcutaneous tissue suspension; facial augmentation; facial suspension; muscular and facial reinforcement; and other uses deemed appropriate by the using surgeon.

Warning: Not for permanent use in Temporo Mandibular Joint applications.

Predicate Devices: The Seare Biomedical Silicone Sheeting configurations are substantially equivalent in material, function, performance, and design to the Silicone Elastomer Sheeting manufactured and marketed by Dow Corning and Bentec Medical. The products have virtually 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. — August 27, 1998

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

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: K983041
Trade Name: Seare Biomedical Silicone Sheeting
Regulatory Class: Unclassified
Product Code: MIB
Dated: August 27, 1998
Received: August 31, 1998

Dear Dr. Seare:

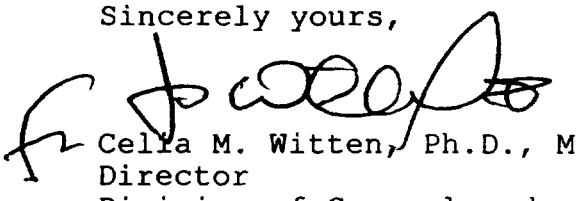
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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): K983041

Device Name: Seare Biomedical Silicone Sheeting

Indications For Use:

For short term application the indications for use are:

- nasal splinting;
- wound dressings;
- management of hypentrophic or keloid scarring;
- to prevent soft tissue fibrosis or bony ankylosis following surgical correction of trismus;
- temporary joint spacers;
- laboratory uses.

For long-term application the indications for use are:

- nasal septal repair;
- orbital floor reconstruction;
- tympanic membrane repair;
- dialysis shunt anchoring;
- duramater repair;
- staged repair of omphalocele;
- for lengthening extra ocular muscles in select cases of strabismus;
- as a protective sheathing to help facilitate neural regeneration and tendon anastomosis;
- as a protective sheathing to help facilitate osteogenesis;
- guided tissue regeneration between teeth and gingival margin, or external ear canal for example;
- other uses deemed appropriate by the using surgeon.

Warning: Not for permanent use in Temporo Mandibular Joint applications.

(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 K983041

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)