

DEC 11 1998

K983630  
**SEARE BIOMEDICAL CORPORATION****510(k) Summary**

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**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 Rods

**Common Name:** Silicone Elastomer Rods

**Classification Name:** Elastomer, Silicone Block

**Substantial Equivalence:** The Seare Biomedical Silicone Rod configurations are substantially equivalent in material, function, performance, and design to the Sil-Tec Rod manufactured and marketed by Technical Products, Inc., and the silicone rods manufactured and marketed by Bentec Medical, Inc.

**Device Description:** Seare Biomedical Silicone Rods are made from specially formulated silicone elastomers designed for implantation. The intended use of the Seare Biomedical silicone rod is for forming a finished device by the surgeon for his or her own custom use. Seare Biomedical Silicone Rods are intended for use in the cosmetic correction of soft tissue deformities, and are shaped at the surgeon's discretion to create a custom implant to aid in the reconstruction process. The Seare Biomedical Silicone Rods will be provided in 15cm or 30 cm lengths, 3FR - 28FR sizes, sterile and nonsterile. The durometers or hardness (Shore A) will range from 5 to 60. The appearance is described as clear to slightly opaque. Surface characteristics will vary from smooth to varying degrees of texturing and porosity.

**Indications For Use:** Seare Biomedical Silicone Rods are intended for use in the cosmetic correction of soft tissue deformities, and are shaped at the surgeon's discretion to create an implant to aid in the reconstruction process. Some uses have been as temporary stents for the formation of new tendon sheaths, as well as other uses in surgical repair procedures demanding a highly inert and flexible rod shaped material as deemed appropriate by the using surgeon.

**Predicate Devices:** The Seare Biomedical Silicone Rod configurations are substantially equivalent in material, function, performance, and design to the Sil-Tec Rod manufactured and marketed by Technical Products, Inc., and the silicone rods manufactured and marketed by Bentec Medical, Inc. The products have comparable indications for use and are offered in the same basic sizes and options.

**Clinical Tests:** None

**Adverse S&E Information:** None

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

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Date



DEC 11 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K983630  
Trade Name: Seare Biomedical Silicone Rods  
Regulatory Class: Unclassified  
Product Code: MIB  
Dated: October 12, 1998  
Received: October 15, 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.

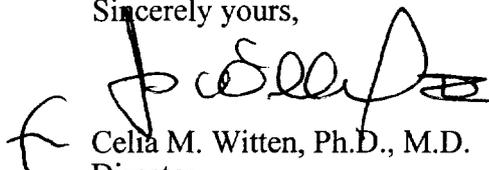
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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.

Page 2 - Mr. William J. Seare, Jr., M.D.

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 'C. Witten', is written over a vertical line that extends from the 'Sincerely yours,' text.

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): K983630

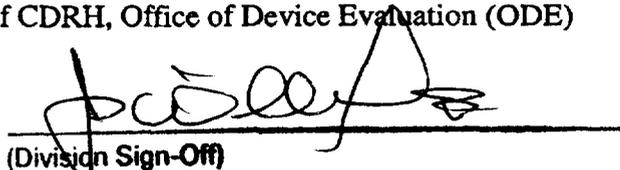
Device Name: Seare Biomedical Silicone Rods

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 K983630

Prescription Use              
(Per 21 CFR 801.109)

OR

Over-The-Counter Use