



K982753

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 Nasal Implants

Common Name: Silicone Elastomer Nasal Implants

Classification Name: Prosthesis, Nose, Internal (per CFR section 878.3680)

Substantial Equivalence: The Seare Biomedical Nasal Implant configurations are substantially equivalent in material, function, performance, and design to the Allied Biomedical Nasal Implants manufactured and marketed by Allied Biomedical

Device Description: Seare Biomedical Nasal Implants are "L" shaped or straight with a concave convex dorsal aspect which reaches from the alar cartilage to the radix. These silicone elastomer rubber implants are made from specially formulated silicone elastomers designed for implantation. Surface characteristics will vary from smooth to varying degrees of texturing and porosity. Seare Biomedical Nasal Implants are intended for use in augmentation and reconstruction of the nasal contour during rhinoplasty. They are intended for insertion via an intraoral or nasal sill incision. The Seare Biomedical Nasal Implants will be available in many sizes and styles, all of which are very similar - differing only by a few millimeters in length and projection. The Seare Biomedical Nasal Implants will be provided sterile and nonsterile. Titanium Oxide and Iron Oxide pigments may be added to the silicone to prevent light translucence to these implants when ordered by the physician. These pigments are well known and widely used in cosmetic surgery implant applications, and will be lot tested for cytotoxicity.

Indications For Use: Seare Biomedical Nasal Implants are intended for use in augmentation and reconstruction of the nasal contour during rhinoplasty. They are intended for insertion via an intraoral or nasal sill incision.

Predicate Devices: The Seare Biomedical Nasal Implant configurations are substantially equivalent in material, function, performance, and design to the Allied Biomedical Nasal Implants manufactured and marketed by Allied Biomedical. The products have identical indications for use and are offered in the same exact size 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



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: K982753
Trade Name: Seare Biomedical Nasal Implants
Regulatory Class: II
Product Code: FZE
Dated: August 03, 1998
Received: August 06, 1998

Dear Dr. Seare:

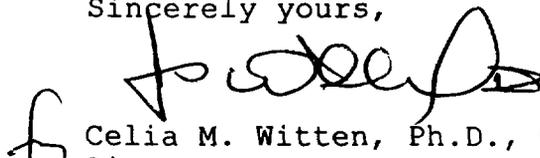
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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): K982753

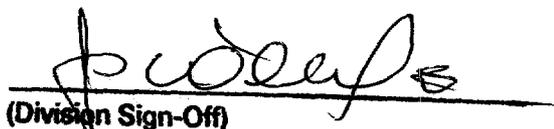
Device Name: Seare Biomedical Nasal Implants

Indications For Use:

Seare Biomedical Nasal Implants are intended for use in augmentation and reconstruction of the nasal contour during rhinoplasty. They are intended for insertion via an intraoral or nasal sill incision.

(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 K9 82753

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____