NOV 2 2 1999

PILLAR
SURGICAL

K992242

Enclosure F

510(k) Summary

Substantial Equivalence

The Pillar Nasal Implant is substantially equivalent to the Silimed. Nasal Implants, marketed by Silimed, LLC. The Pillar Nasal Implant is made from identical liquid elastomer materials and manufacturing processes as the predicate device.

Intended Use

The intended use of the Pillar Nasal Implant is to augment or reconstruct facial nasal deformities caused by facial trauma or congenital defects. The Pillar Nasal Implant is implanted using the same accepted surgical methods of the predicate device.

Labeling

The labeling for this device will comprise a label for the inner package and a label for the outer box. Catalog numbers and sizes will be clearly displayed on the labels. A "Package Insert" will contain instructions for sterilization and indications for use. Product promotional material will depict size, shape and material firmness of the implant.

Physical and Chemical Properties

The physical properties of this device are the same as the predicate device in that equivalent materials will be used in manufacturing. The raw materials are Nusil's MED 4211 unrestricted silicone fluid from Nusil Technologies, Inc. The durometers or hardness (shore A) of each implant will range from 5 to 30. The appearance is described as clear to opaque. Tensile strength averages 700 psi and the percent of elongation is over 400 percent. Raw material are certified and tested to comply with the requirements of the manufacturer. For more information, see FDA master-file MAF 612.

PO Box 8141 • La Jolla, CA 92038-8141 • (800) 367-0445 • (619) 525-7908 • fax (619) 295-0847

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 1999

Mr. Rob Fritzenkotter
Pillar Surgical
P.O. Box 8141
La Jolla, California 92038

Re: K992242
Trade Name: Nasal, Dorsal Columella, and Nasal Dorsum Implant
Regulatory Class: II
Product Code: FZE
Dated: November 4, 1999
Received: November 5, 1999

Dear Mr. Fritzenkotter:

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,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K992242

DEVICE NAME: _____

INDICATIONS FOR USE:

Each Pillar Nasal Implant is indicated for the augmentation or reconstruction of nasal eminence deficiencies, whether congenital or acquired by trauma or disease.

NPO for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992242

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1