K982294

SEP 18 1998

APPENDIX F

510(k) Summary

1.0 Date Prepared

June 25, 1998

2.0 Submitter (Contact)

Roy Berens
Xomed Surgical Products
Jacksonville, FL
(904) 296-6454

3.0 Device Name

Proprietary Name: Xomed Silicone Pre-form Blocks

Common Name(s): Silicone Block/Strip

Classification Name: ENT synthetic polymer material

4.0 Device Classification

ENT : Procode 77KHJ Class II ; 21 CFR 874.3620 Tier 3

General and Restorative: Unclassified

5.0 Device Description

Xomed Silicone Pre-form Blocks are sterile supplied implants made from silicone elastomer molded into a pre-form sizes as specified on the product label. Metric graduations on the implant surface helps in sizing the implant for patient need. The implants are to be trimmed and shaped to size by the surgeon for individual patient needs. The devices are intended for single patient use only. As a prescription device, the surgeon should be familiar with the skills and training for laryngeal reconstruction and vocal fold augmentation with silicone implants.

6.0 Intended Use

The Silicone Pre-form Blocks are intended for use as an implant material for surgical to aid in surgical reconstructions as a space occupying material in laryngeal surgical procedure for vocal fold medialization and augmentation.

7.0 Substantial Equivalence

Xomed markets both silicone blocks and strips for implant uses in head and neck surgery by K970910. The Silicone Pre-form Blocks are substantially equivalent to these predicate products in that they are made from the same material which has satisfactory biocompatibility approval for implant applications. Additionally, the Silicone elastomer Pre-form Blocks are similar to the Montgomery Thyroplasty Implants, Boston Medical Products K972317 for the intended use in thyroplasty procedures involving medialization and augmentation of the vocal fold. The difference is the Xomed Pre-form Blocks are to be trimmed to final shape and size by the surgeon for the individual patient needs while the Montgomery silicone elastomer implants are predetermined sized silicone augmentation devices requiring no alteration at surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 18 1998

Roy Berens
Manager, Quality System Regulations
Xomed Surgical Products, Inc.
6743 Southpoint Drive N.
Jacksonville, FL 32216

Re: K982294
Xomed Silicone Pre-Form Blocks
Dated: June 25, 1998
Received: June 30, 1998
Regulatory class: II
21 CFR 874.3620/Procode: 77 KHJ

Dear Mr. Berens:

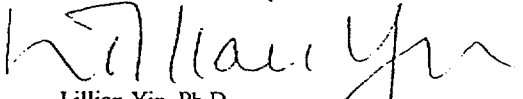
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B

Intended Use Statement

510(k) Number (if known):_____

Device Name:
Silicone Pre-form Blocks

Indications for Use:
The Silicone Pre-form Blocks are indicated as an implant material to aid in surgical reconstructions as a space occupying material in laryngeal surgical procedures for vocal fold medialization and augmentation.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982294