NOV 3 1998

XOMED®

X. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS K 982870

1.0 Date Prepared

August 12, 1998

2.0 Submitter (Contact)

Roy Berens, Manager Quality System Regulations
Xomed Surgical Products
Jacksonville, FL 32216
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3.0 Device Name

Proprietary Name:	Xomed EpiFilm™ Otologic Lamina
Common Name(s):	Synthetic Polymer Implant Material Surgical Implant Polymer Material Surgical Adjunct Polymer Material
Classification Name:	Ear, nose, and throat synthetic polymer material

4.0 Device Classification

Ear, nose, and throat synthetic polymer material
ProCode KHJ
Class II ; 21 CFR 874.3620

5.0 Device Description

Xomed EpiFilm Otologic Lamina is a biomaterial composed of HYAFF® an ester of hyaluronic acid, a naturally occurring constituent of the extracellular matrix. The transparent lamina has micro-perforations to allow permeability facilitating drainage of exudate at the surgical site.

6.0 Intended Use

The Xomed EpiFilm™ Otologic Lamina is intended for use as an implant material to aid in surgical repairs and as an adjunct to aid in the natural healing process in various otologic procedures. EpiFilm™ Otologic Lamina is indicated for use in myringoplastic and tympanoplastic surgical procedures.

7.0 Substantial Equivalence

EpiFilm™ Otologic Lamina is an ENT polymeric implant material for prescription use supplied sterile in individual pouches containing a single 2.5 cm x 2.5 cm square of the device. EpiFilm™ squares feature microholes to provide a permeable surface and are intended for aid in surgical repairs and is an adjunct to aid in the natural healing process in various otologic procedures by providing a biocompatible covering surface.

Both the subject and predicate devices are intended for use as long term implant materials for ENT surgical repairs. Both use biocompatible polymeric materials in the form of thin sheeting which may be trimmed to meet the specific needs of the patient, are sterile, single use. The difference is that the predicate devices are made of silicone whereas EpiFilm™ is made of the benzyl ester of hyaluronic acid which typically dissolves in about six (6) to eight (8) weeks after implantation.

The material comprising EpiFilm™ has been subjected to extensive biocompatibility testing according to the ISO/EN standards for material testing for toxicity and biocompatibility. The material has been demonstrated non-toxic and biocompatible according to ISO 10993 standards, and in clinical study has presented no new issues of safety or effectiveness for the intended use.

In conclusion, Xomed EpiFilm™ Otologic Lamina has the same intended use as the predicate devices and differs only in the material which has been shown as biocompatible, as based on the data in the submission, and raises no new issue of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 1998

Roy Berens
Manager, Quality Systems Regulations
Xomed
6743 Southpointe Dr. N.
Jacksonville, FL 32216-0980

Re: K982870
EpiFilm® Otologic Lamina
Dated: October 7, 1998
Received: October 8, 1998
Regulatory class: II
21 CFR 874.3620/Procode: 77 KHJ

Dear Mr. Berens:

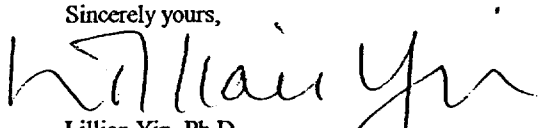
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Intended Use Statement

510(k) Number (if known): K 982870

Device Name: EpiFilm™ Otologic Lamina

Indications for Use: The Xomed EpiFilm™ Otologic Lamina is intended for use as an implant material to aid in surgical repairs and as an adjunct to aid in the natural healing process in various otologic procedures.

(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. Ergo

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982870