JUL 16 1998

Exmoor Plastics

FDA/CDRH/ODE/DMC

4 May 98 20123

RECEIVED

Your Ref: Our Ref: MB/PAS

Contact: Margaret Blackmore

27 April 1998

Re: K972700

Summary of Safety and Effectiveness

Trade Name:
1. Exmoor Attic and Mastoid Antrum Middle Ear Implant
2. Exmoor Middle Ear Aeration Sheeting

Common Name:
1. Attic and Mastoid
2. Aeration Sheeting

Classification Name: Prosthesis, Ear, Internal

Predicate Devices: Exmoor Plastics SRS/1, 510K number K911503/A

Description of Device: The devices are small, shaped pieces of silicone rubber sheet. They are intended for long term use, i.e. it is not necessary for this material to be removed.

Intended Use:

1. **Attic and Mastoid** - Following tympano-mastoid surgery, this implant is placed into the attic and back into the mastoid. It is intended to improve aeration from the middle ear into the attic and the mastoid.

2. **Aeration Sheeting** - Following middle ear surgery, after removal of middle ear adhesions and following reconstruction of the tympanic membrane and ossicular chain, this implant is inserted into the mouth of the eustachian tube, covering the promontory, under the handle of the malleus and covering the middle ear. This implant is designed to reduce adhesions in the middle ear following surgery.

Comparison with Predicate Devices:	All these devices are cut from exactly the same implantable silicone rubber sheeting as the Exmoor Plastics SRS/1. This is for the convenience of the surgeon, saving time in the operating room and avoiding waste of expensive implantable material in the form of offcuts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 1998

Margaret Blackmore
Regulatory Affairs
Exmoor Plastics Ltd.
Lisieux Way, Taunton
TA1 2LB, U.K.

RE: K972700
Exmoor Attic and Mastoid Antrum
Middle Ear Plant
Exmoor Middle Ear Aeration Sheeting
Dated: April 15, 1998
Received: April 20, 1998
Regulatory Class: II
21 CFR 874.3620/Procode: 77 KHJ

Dear Ms. Blackmore:

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

510(k) Number (if known): K972700

Device Name: 1. EXMOOR ATTIC AND MASTOID ANTRUM MIDDLE EAR IMPLANT

Indications for Use: This implant is designed to aerate the attic and mastoid antrum following tympanomastoid surgery. This silastic implant is designed to be placed in the attic and back into the mastoid antrum following mastoidectomy/ tympanoplasty surgery. The narrow end is placed under the head of the malleus when present and back into the mastoid antrum to enhance mucosa regrowth.

Device Name: 2. EXMOOR MIDDLE EAR AERATION SHEETING

Indications for Use:

1. This implant is designed to reduce adhesions in the middle ear following tympanoplasty surgery.

2. Made with medical grade silicone, this implant was designed to be used following middle ear surgery to prevent middle ear adhesions, especially from the malleus to the promontory, or from the ear drum to the inner ear.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972700

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)