K981045

Attachment 1

MAY 20 1998

MB/PAS/DMR/1/C/20

Contact: Margaret Blackmore

10 March 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name:	Exmoor Teflon Loop Replacement Prosthesis
Common Name:	Teflon Loop
Classification Name:	Prosthesis, Ear, Internal
Predicate Devices:	a. Causse Tef-Piston - Xomed Treace b. Cause Tef-Piston Large Loop - Xomed Treace c. Shea Malleus Teflon Piston - Richards d. Causse Modified Teflon Piston - Richards
Description of Device:	The Exmoor Teflon Loop will be offered in two sizes. Each comprises one element, the shaft of which is 6.0mm long and is either 0.4mm or 0.6mm in diameter. The loop has an internal dimension of 0.7mm to fit the malleus for the replacement of the stapes and the incus. Secure closure is provided by "plastic memory". The outside diameter of the loop is either 1.5mm or 1.9mm.
Intended Use:	This prosthesis can be used to reconstruct defects of the stapes and the incus. POR P
Comparison with Predicate Devices:	The Exmoor Teflon Loop is made of exactly the same material as all four of the predicate devices and is intended to perform exactly the same function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

Margaret Blackmore
Regulatory Affairs
Exmoor Plastics, Inc.
Lisieux Way
Taunton, TA1 2LB
United Kingdom

Re: K981045
Teflon Loop Replacement Prosthesis
Dated: March 12, 1998
Received: March 20, 1998
Regulatory Class: II
21 CFR 874.3450/Procode: 77 ETB

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

Attachment 2

RAM/19/A/1

DMR/1/C/20

510(k) Number (if known): K981045

Device Name: EXMOOR TEFLON LOOP REPLACEMENT PROSTHESIS

Indications for Use:

This prosthesis can be used to reconstruct an absent or defective stapes and incus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981045

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)