Exmoor
Plastics

K974008

K974008

MAY 13 1998

Your Ref: Our Ref: MB/PAS/K974008

Contact: Margaret Blackmore

14 April 1998

SUMMARY OF SAFETY & EFFECTIVENESS

Trade Name:	Pfleiderer's Intratympanic Catheter
Common Name:	Intratympanic Catheter
Classification Name:	Catheter Eustachian, General and Plastic Surgery
Predicate Devices:	Portex Remote Injection Catheter
Description of Device:	This single use device consists of a silicone rubber catheter, 21cm in length, with a spring loaded Luer lock at one end and a soft rubber flange, to retain the device in the middle ear, at the other.
Intended Use:	For use as a closed system for the repeated, safe delivery of therapeutic agents into the middle ear, to facilitate the control of disabling vertigo arising from active unilateral Meniere's Disease.
Comparison with Predicate Devices:	The Portex Remote Injection Catheter is constructed of nylon tubing, with a Luer connector at one end and a Luer lock mount at the other; similar. The Exmoor Intratympanic Catheter is constructed of silicone tubing with a silicone bevelled flange at one end and a one-way Luer valve at the other. The function is the same, in that they both deliver medication. The fit is similar, except that a silicone flange replaces the lock mount, making it possible for the doctor or patient to perform a relatively, pain-free, self-administration of his/her medication.

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Co. Reg. No:
2075762 (Eng)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 1998

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

Re: K974008
Pfleiderer's Intratympanic Catheter
Dated: April 14, 1998
Received: April 17, 1998
Regulatory class: II
21 CFR 874.3880/Procode: 77 ETD

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

RAM/19/A/1

[redacted]

Device Listing Number: A875609

510(k) Number (if known): K974008

Device Name: Pfleiderer's Intratympanic Catheter

Indications for Use:

Incapacitating unilateral Menière's Disease

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Bergman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974008

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