Exmoor Plastics

K973587

JAN 23 1998

Your Ref: Our Ref: MB/PAS/DMR/1/H/48

10 November 1997

Contact: Margaret Blackmore

Ref: K.973587

Summary of Safety and Effectiveness

Trade Name: Exmoor Tympanocentesis Kit

Common Name: Tympanocentesis Kit

Classification Name: Tube, Ear, Suction

Predicate Devices: Xomed, Juhn Tym-Tap (ref. 14-19010)
Sherwood, Specimen Trap (ref. 8884-724500)
Storz, Senturia Specimen Collectors (ref. NO600/NO601)
Storz, Alden-Senturia Specimen Collector (ref. NO605)

Description of Device: This single use device is designed to collect specimens of middle ear fluid from behind an intact tympanic membrane and comprises the following:

- polythene disposal bag
- glove (examination)
- 'Disposafe' (for sharps)
- fenestrated surgical ear drape
- mop
- label
- vial assembly
- suction tube (hand-piece)
- myringotome (aspirating)
- specimen bag (laboratory)
- aural speculum, 2.5mm

It has been sterilized by gamma irradiation and is ready for use.

Intemded Use: This device is intended to collect middle ear fluid within the viscosity range of sae 30-50 for laboratory analysis.

Comparison with Predicate Devices:

1. Juhn Tym-Tap, (ref. 14-19010), manufactured by Xomed, is similar, but does not feature a myringotome to puncture the tympanum. It is disposable. Catalogue entry enclosed.

2. The 40cc Specimen Trap (ref. 8884-724500). manufactured by Sherwood, has neither myringotome, nor micro-bore suction tubing. It is disposable. Picture enclosed.

3. Senturia Specimen Collectors, (ref. N0600/N0601), and the Alden-Senturia Specimen Collector (N0605), manufactured by Storz. These are reusable. Catalogue entry enclosed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 1998

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

Re: K973587
Trade Name: TK/1 Tympanocentesis Kit
Regulatory Class: I/21 CFR 874.4420
Product Code: 77 JZF
Dated: November 25, 1997
Received: December 1, 1997

Dear Mr. 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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/dsmamain.html".

Sincerely yours,

for David A. Seguin

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

Device Listing Number: A895746

510(k) Number (if known): K973587

Device Name: Exmoor Tympanocentesis Kit

Indications for Use:

Requirement for aspiration and analysis of middle ear fluid from behind an intact tympanic membrane (ear drum)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973587

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

(Optional Format 1-2-96)