



**Exmoor
Plastics**

ATTACHMENT 1

K974007



Your Ref:

Our Ref:

MB/PAS/A.8756106

Contact: Margaret Blackmore

14 October 1997

510K Pre-Market Notification Summary

Trade Name: Shah Permavent

Common Name: Permavent

Classification Name: Tympanostomy Tube

Predicate Devices: Richards Shah Perma-vent Tube, Cat. No. 24-0012
54-0002
24-0026
Richards Per-Lee Drain Tube, Cat. No. 24-0026
Xomed-Treace Per-Lee Vent Tube, Cat. No. 10-
25025

Description of Device: A middle ear ventilation tube, fabricated in silicone rubber and featuring a single, circular, bevelled flange.

Intended Use: The device is intended to ventilate the middle ear cleft.

Comparison with Predicate Devices:

The Richards Shah Permavent Ventilation Tube has a very similar form, except for the mesh reinforcement of the flange. Its fit and function are exactly similar.

The Richards, Per-Lee drain tube has an exactly similar fit and function. The form is very similar but is larger overall.

The Xomed-Treace, Per-Lee vent tube is exactly similar in all respects to the Richards version.



Exmoor Plastics Ltd., Lisieux Way, Taunton, TA1 2LB, U.K.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 1997

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

Re: K973273 *K974007*
Exmoor Shah Permanent Tympanostomy Tube
Dated: October 14, 1997
Received: October 21, 1997
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 requirement, 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/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): K974007

Device Name: SHAH PERMAVENT

Indications for Use:

In the treatment of:

1. otitis media with effusion (glue ear)
2. eustachian tube dysfunction
3. other condition requiring ventilation of the middle ear cleft, e.g. retraction pockets in the tympanic membrane, adhesive otitis media, where long-term ventilation is indicated.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K974007

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)