



Your Ref:

Our Ref:

MB/PAS/A895748

JAN 27 1998

K974224

Contact: Margaret Blackmore

4 November 1997

Summary of Safety and Effectiveness

~~510K Pre-Market Notification Summary~~

Trade Name:

Endolymphatic Sac to Mastoid T-Shunt

Classification Name:

Shunt Endolymphatic

Predicate Devices:

Richards Endolymphatic Shunt Tube (Austin Modification)
Richards Silicone Elastomer Endolymphatic Shunt Tube (House type)

Description of Device:

This device is a small, T-shaped piece of silicone rubber sheet, approximately 8.5mm x 1mm x 0.125mm. The T-bar is 5mm wide.

Intended Use:

Endolymphatic Sac fluid increases during Meniere's disease attacks. This simple 'T' type endolymphatic sac shunt is designed to act as a continuous drain, allowing endolymphatic sac fluid to be shunted into the Mastoid. The shunt is placed in the sac along with decompression of the sac and the adjacent dura.

Comparison with Predicate Devices:

This shunt differs from the House type and the Austin modification in its form. The 'T' bar stays in the sac and the long portion comes out through a separate incision in the sac, thus preventing extrusion. The flat form is easier to insert and stays in place, since it is more anatomical, like the flatness of the sac. The fit of this device is very similar except that it does not require insertion into the subarachnoid space.

The function of this device is the same as the two predicates.





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 1998

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

Re: K974224
Endolymphatic T-Shunt
Dated: December 18, 1997
Received: December 29, 1997
Regulatory class: II
21 CFR 874.3820/Procode: 77 ESZ

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): K974224

Device Name: ENDOLYMPHATIC SAC TO MASTOID T-SHUNT

Indications for Use:

Endolymphatic Sac fluid increases during Meniere's disease attacks. This simple 'T' type endolymphatic sac shunt is designed to act as a continuous drain, allowing endolymphatic sac fluid to be shunted into the Mastoid. The shunt is placed in the sac along with decompression of the sac and the adjacent dura.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson

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

510(k) Number K974224

K974224

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use