K082188

Acclarent

SEP 1 9 2008

APPENDIX A: 510(k) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Keri Yen Regulatory Affairs Specialist Phone: (650) 687-5874 Fax: (650) 687-4449
Date of Submission:	August 1, 2008
Device Trade Name:	TBD
Common Name:	Tympanostomy Tube
Device Classification:	Class II
Regulation Number:	21 CFR 874.3880
Classification Name:	Tube, Tympanostomy
Product Code:	ETD
Predicate Devices:	MicroMedics Otological Ventilation Tube (K830228) Xomed Activent Ventilation Tube (K941407) Exmoor Plastics Ltd. Donaldson Vent-Mini Tube (K911580)
Device Description:	The Tympanostomy Tube is a silicone tube that is intended to provide ventilation and/or drainage to the middle ear. The Tympanostomy Tube is available in two types: Donaldson and Paparella.
Indications for Use:	Conditions for which tympanostomy tubes are indicated include: o Chronic otitis media with effusion (serous, mucoid, or purulent) o Recurrent otitis media that fails to respond to conventional medical treatment o A history of persistent high negative middle ear pressure which may be associated with conductive hearing loss, otalgia, vertigo and/or tinnitus. o Retraction pocket of the tympanic membrane.
Technological Characteristics:	The Tympanostomy Tube, when inserted through the tympanic membrane, is intended to ventilate the middle ear. It also allows for drainage of fluid resulting from otitis media.

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Performance Data:	The Tympanostomy Tube met all performance acceptance criteria.
Summary of Substantial Equivalence:	The Tympanostomy Tube is substantially equivalent to the predicate devices as confirmed through relevant tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2008

Acclarent, Inc.
c/o Keri Yen
1525-B O'Brien Drive
Menlo Park, CA 94025

Re: K082188
Trade/Device Name: Tympanostomy Tube
Regulation Number: 21 CFR 874.3880
Regulation Name: Tube, tympanostomy
Regulatory Class: II
Product Code: ETD
Dated: August 1, 2008
Received: August 4, 2008

Dear Ms. Yen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082188

Trade Name: TBD

Common Name: Tympanostomy Tube

Indications For Use: Conditions for which tympanostomy tubes are indicated include:

- Chronic otitis media with effusion (serous, mucoid, or purulent)
- Recurrent otitis media that fails to respond to conventional medical treatment
- A history of persistent high negative middle ear pressure which may be associated with conductive hearing loss, otalgia, vertigo and/or tinnitus.
- Retraction pocket of the tympanic membrane.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen H Baker

...vision Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K082188

(Posted November 13, 2003)