K103595

Acclarent

APR - 1 2011



## APPENDIX A: 510(k) SUMMARY

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|---|---|
| **Sponsor/Submitter:** | Acclarent, Inc.<br>1525-B O'Brien Drive<br>Menlo Park, California 94025 |
| **Contact Person:** | Gurvinder Singh Nanda<br>Regulatory Affairs Manager<br>Phone: (650) 687-5414<br>Fax: (650) 687-4449 |
| **Date of Submission:** | January 25, 2011 |
| **Device Trade Name:** | TBD |
| **Common Name:** | Acclarent Tympanostomy Tube and Tympanostomy Tube Delivery System |
| **Device Classification:** | Class II |
| **Regulation Number:** | 21 CFR 874.3880 |
| **Classification Name:** | Tube, Tympanostomy |
| **Product Code:** | ETD |
| **Predicate Devices:** | Heinz Kurz GmbH Medizintechnik Trocar Ventilation Tube (K830228)<br>Acclarent Tympanostomy Tube (K082188)<br>Exmoor Plastics Ltd. Myringotomy Kit (K980828) |
| **Device Description:** | The Tympanostomy Tube Delivery System is a device that penetrates the tympanic membrane and inserts the Acclarent Tympanostomy Tube with a button controlled activation. |
| **Indications for Use:** | The Tympanostomy Tube Delivery System is intended to provide a means to create a myringotomy with insertion of a preloaded Paparella type tympanostomy tube.<br><br>Conditions for which tympanostomy tubes are indicated include:<br>o Chronic otitis media with effusion (serous, mucoid, or purulent)<br>o Recurrent otitis media that fails to respond to conventional medical treatment<br>o A history of persistent high negative middle ear pressure which may be associated with conductive hearing loss, otalgia, vertigo and/or tinnitus.<br>o Retraction pocket of the tympanic membrane. |

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| **Technological Characteristics:** | The Tympanostomy Tube Delivery System is a mechanical device that can create a myringotomy and deliver the Acclarent Tympanostomy Tube. The Acclarent Tympanostomy Tube is provided pre-loaded in the subject device. |
| **Performance Data:** | Acclarent conducted a prospective, multi-center, single arm clinical study to evaluate the performance and safety of the Acclarent TTDS device for the placement of the Acclarent Tympanostomy Tube in subject ears indicated for such treatment for chronic OME or recurrent AOM.<br><br>A total of 101 ears were enrolled in 53 pediatric subjects by 4 investigators at 4 study sites. All study procedures were performed under general anesthesia in the operating room. The overall Device Success rate of the TTDS device was 94% (95/101). The 6% device non-success rate was attributable to failure of the devices to fully deploy the tubes across the tympanic membranes. This anticipated failure mode can occur if the device tip is not fully registered against the tympanic membrane. This mode was not associated with any adverse sequelae and in each case, standard otologic tools were used to manually place a tympanostomy tube. 100% (101/101) of enrolled ears received their indicated treatment.<br><br>At the one-week post-procedure follow-up visit, retention of the Acclarent Tympanostomy Tube was observed at a rate of 98.95% (94/95). Consistent with the rates reported in the clinical literature, tube occlusion was observed in 5% of tubes at follow-up: the incidence of non-functional tympanostomy tubes caused by occlusion is relatively common, ranging from 7% to 37% (Tsao, BA *et al. Otolaryngol Head Neck Surg*, 128(6):870-874, 2001) and has been known to occur in a wide variety of tubes (Weigel, MT *et al. Laryngoscope*, 99:252-256, 1989).<br><br>The Tympanostomy Tube Delivery System met all the study performance acceptance criteria. |
| **Summary of Substantial Equivalence:** | The Acclarent Tympanostomy Tube and Tympanostomy Tube Delivery System is substantially equivalent to the predicate devices as confirmed through dimensional attributes. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Acclarent, Inc.
c/o Gurvinder Singh Nanda, Ph.D.
Regulatory Affairs Manager
1525-B O'Brien Drive
Menlo Park, CA 94025

APR - 1 2011

Re: K103595
Trade/Device Name: Tympanostomy Tube Delivery System
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: February 24, 2011
Received: February 28, 2011

Dear Dr. Nanda:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

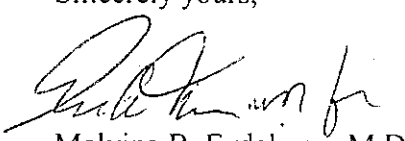
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

Acclarent



## APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103595

Trade Name: TBD

Common Name: Tympanostomy Tube Delivery System

Indications For Use: The Tympanostomy Tube Delivery System is intended to provide a means to create a myringotomy with insertion of a preloaded Paparella type tympanostomy tube.

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)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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*(Posted November 13, 2003)*