January 16, 2018

Acclarent, Inc.
James Garvey II
Associate Director
33 Technology Drive
Irvine, CA 92618

Re: K171761
Trade/Device Name: ACCLARENT AERA® Eustachian Tube Balloon Dilation System
Regulation Number: 21 CFR 874.4180
Regulation Name: Eustachian Tube Balloon Dilation System
Regulatory Class: Class II
Product Code: PNZ
Dated: December 14, 2017
Received: December 15, 2017

Dear James Garvey II:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Eric A. Mann -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171761

Device Name
ACCLARENT AERA Eustachian Balloon Dilation System

Indications for Use *(Describe)*
The ACCLARENT AERA® Eustachian Tube Balloon Dilation System is intended to dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in patients ages 18 and older.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

K171761

Sponsor/Submitter:	Acclarent, Inc. 33 Technology Drive Irvine, California 92618
Contact Person:	James Patrick Garvey II Associate Director, Regulatory Affairs Phone: 949-789-8505 Fax: (650) 687-4449
Date of Submission:	June 12, 2017
Device Trade Name:	ACCLARENT AERA® Eustachian Balloon Dilation System
Common Name:	Eustachian Tube Balloon Dilation Device
Device Classification:	Class II
Regulation Number:	21 CFR 874.4180
Classification Name:	Eustachian Tube Balloon Dilation System
Product Code:	PNZ
Establishment Registration Number	3005172759
Predicate Devices:	ACCLARENT AERA® Eustachian Tube Balloon Dilation System (DEN150056) Entellus XprESS ENT Dilation System (K163509)
Device Description:	The ACCLARENT AERA® Eustachian Tube Balloon Dilation System includes a Eustachian Tube Balloon Catheter and Guide Catheter designed specifically for use in accessing and dilating the Eustachian Tube. The system is used with the following additional devices: the ACCLARENT® SE Inflation Device (or ACCLARENT® Balloon Inflation Device). The ACCLARENT® SE Inflation Device or ACCLARENT® Balloon Inflation Device is used to inflate the balloon. All devices are provided sterile for single-patient use. The ACCLARENT AERA® Eustachian Tube Balloon Dilation System includes is a 6x16mm (inflated diameter x length) flexible Balloon Catheter with an integrated shaft and a nylon balloon at the distal tip. The non-compliant balloon is designed to dilate the cartilaginous portion of the

	Eustachian tube. The shaft consists of dual lumen tubing with an actuator component that is designed to assist in rotation and advancement of the balloon catheter. The balled catheter tip (aka, "blueberry tip") on the balloon catheter is designed to restrict advancement of the device into the bony portion of the Eustachian tube, known as the isthmus. There is an endoscopic marker placed at the proximal taper of the balloon to aid in positioning under direct endoscopic visualization. The AERA Guide Catheter is anatomically designed to facilitate AERA Balloon Catheter access to the Eustachian tube. The AERA Guide Catheter incorporates an atraumatic distal tip and distal angled tip profile that facilitates access to the Eustachian tube. The Guide Catheter supplied with the ACCLARENT AERA® Eustachian Tube Balloon Dilation System contains a lubricious inner liner to allow smooth passage for the balloon catheter and includes a hypotube for rigidity.
Indications for Use:	The ACCLARENT AERA® Eustachian Tube Balloon Dilation System is intended to dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in patients ages 18 and older.
Contraindications:	The ACCLARENT AERA® Eustachian Tube Balloon Dilation System is contraindicated for use in a Eustachian tube with an ipsilateral carotid artery that is dehiscent into the ET lumen or history of ipsilateral patulous Eustachian tube.
Technological Characteristics:	The ACCLARENT AERA® Eustachian Tube Balloon Dilation System is a device that allows for dilation of the cartilaginous portion of the Eustachian tube. Eustachian tube dilation is achieved via a noncompliant balloon located on the distal end of the device which is inflated with sterile saline or sterile water.
Substantial Equivalence:	The ACCLARENT AERA® Eustachian Tube Balloon Dilation System device has expanded indications for use, identical intended use, and identical fundamental scientific technology as the predicate device. The AERA device is substantially equivalent to the predicate devices.
Performance Data:	Bench testing has met all acceptance criteria for attributes such as dimensional attributes, cycle fatigue, balloon burst, and bond separation. Testing has shown that the ACCLARENT AERA® Eustachian Tube Balloon Dilation System is biocompatible. The sterilization process has been validated per AAMI/ANSI/ISO 11135: 2014 and demonstrated a sterility assurance level of 10^{-6}. The method used for sterilization validation is the overkill (half-cycle approach) in a fixed chamber. Testing of ethylene oxide residuals met ISO 10993-7:2008 requirements. The subject device is not tested nor labeled as "non-pyrogenic". Packaging shelf life was established at one year via accelerated aging per ASTM F1980-07.

The performance data demonstrate that the device performs as intended.

Although use of AERA device under local anesthesia alone has not been studied in a randomized controlled trial, evidence of its use under topical/local anesthesia along with sedation and analgesia is available in the literature. [1]

In addition, real-world clinical data collected from 25 patients from two sites supports the use of AERA device under local/topical anesthetic with appropriate patient preparation which may include supplemental medication for patient management.

Conclusion:

The technological characteristics of the ACCLARENT AERA® Eustachian Tube Balloon Dilation System are substantially equivalent to the predicate devices for use in mechanically dilating the Eustachian tube. Performance testing has demonstrated that the device is safe and effective. Additional clinical testing was not required to demonstrate safety and efficacy of the device. The ACCLARENT AERA® Eustachian Tube Balloon Dilation System is substantially equivalent to the predicates.

[1] Luukkainen V, Kivekäs I, Hammarén-Malmi S, Rautiainen M, Pöyhönen L, Aarnisalo AA, Jero J, Sinkkonen ST. Balloon Eustachian tuboplasty under local anesthesia: Is it feasible? Laryngoscope. 2017 Feb 03. doi:10.1002/lary.26488