December 13, 2023

Acclarent, Inc.
Kamrie Sarnosky
Senior Regulatory Specialist
31 Technology Drive
Irvine, California 92618

Re: K230742
Trade/Device Name: ACCLARENT AERA Eustachian Tube Dilation System
Regulation Number: 21 CFR 874.4180
Regulation Name: Eustachian tube balloon dilation system
Regulatory Class: Class II
Product Code: PNZ
Dated: November 12, 2023
Received: November 13, 2023

Dear Kamrie Sarnosky:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230742

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.

For patients ages 8-17 years, the ACCLARENT AERA® Eustachian Tube Balloon Dilation System, alone or in combination with adjunctive procedures, is intended to treat patients with objective signs of persistent obstructive Eustachian tube dysfunction from inflammatory pathology, resulting in chronic otitis media with effusion and are refractory to at least one surgical intervention for persistent obstructive Eustachian tube dysfunction.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K230742 - 510(k) Summary

Sponsor/Submitter:	Acclarent, Inc. 31 Technology Drive Irvine, CA 92618
Contact Person:	Kamrie Sarnosky Senior Program Lead, Regulatory Affairs Phone: 931-551-5023 Fax: (949) 450-6886
Date of Submission:	March 16, 2023
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
Predicate Devices:	ACCLARENT AERA® Eustachian Tube Balloon Dilation System (K171761)
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. For patients ages 8-17 years, the ACCLARENT AERA® Eustachian Tube Balloon Dilation System, alone or in combination with adjunctive procedures, is intended to treat patients with objective signs of persistent obstructive Eustachian tube dysfunction from inflammatory pathology, resulting in chronic otitis media with effusion and are refractory to at least one surgical intervention for persistent obstructive Eustachian tube dysfunction.
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. The technological characteristics of the device are identical to those cleared in K171761.
Substantial Equivalence:	The ACCLARENT AERA® Eustachian Tube Balloon Dilation System device has expanded indications for use and identical fundamental scientific technology as the predicate device. The AERA device is substantially equivalent to the predicate device.
Performance Data:	Previously submitted 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 was validated per AAMI/ANSI/ISO 11135-1: 2007 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. Previously submitted performance data demonstrate that the device performs as intended and no new testing was performed for this submission.
Clinical Data:	A systematic literature review was conducted per PRISMA guidelines to assess safety and efficacy of BDET in the pediatric population inclusive of both non-Acclarent and Acclarent devices. Real-world evidence, with data from published literature and data provided by established physicians, was analyzed to evaluate the safety and effectiveness of the AERA Eustachian Tube Balloon Dilation System in pediatric patients. The

data supported substantial equivalence for the pediatric patient population of ages 8-17. Equivalence of the anatomy was demonstrated with several articles which evaluated Eustachian tube anatomy in the expanded patient population. Based on CT scan reviews, the anatomy of the target patient population was found to be similar to that of the predicate age group with no issues of safety raised.

Real-world evidence was reviewed consisting of ETBD with AERA in patients ages 8-17 years with objective signs of persistent obstructive Eustachian tube dysfunction from inflammatory pathology, resulting in chronic otitis media with effusion. This evidence supports that ETBD is comparable if not superior to tympanostomy tube placement alone in the treatment of chronic otitis media with effusion in the pediatric population. A review of safety data in the expanded population was found to be safe with no serious adverse events reported after ETBD and a minor AE rate in 8.2% of patients in the expanded age group. Efficacy data in 20 ears from patients aged 8-17 years with COME showed an improvement in tympanometry in 75% of procedures. A total of 84% of ears were failure-free after a mean of 2.7 years of follow-up (failure was defined as whether further surgery was needed to treat the patient's ETD, eg. tympanostomy tube insertion or revision ETBD).

Conclusions:

The AERA Eustachian Tube Balloon Dilation System is substantially equivalent to the predicate device based on the following: (1) clinical data obtained from Real-World Evidence, including a systematic literature review, review of adverse events, CT studies demonstrating anatomical Eustachian tube equivalence, for which data analysis showed that the BDET procedure outcomes were successful to expand the indicated population to 8-17 years of age with persistent otitis media with effusion due to inflammatory pathology and refractory to at least one surgical intervention and (2) equivalence in terms of fundamental scientific technology based on identical design and principles of operations.

Summary of Substantial Equivalence:

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. Previous 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 predicate.