February 19, 2026

Acclarent, Inc.
Kweku Biney
Regulatory Affairs Manager
31 Technology Dr. Suite 200
Irvine, California 92618

Re: K253612
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: November 18, 2025
Received: November 18, 2025

Dear Kweku Biney:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

SHUCHEN PENG -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253612

Please provide the device trade name(s).

Acclarent AERA Eustachian Tube Balloon Dilation System

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

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

510(k) SUMMARY – K253612

Sponsor/Submitter:	Acclarent, Inc. 31 Technology Drive Irvine, California 92618
Contact Person:	Kweku Biney Manager, Regulatory Affairs Phone: 804-484-9713 Email: Kweku.biney@integralife.com
Date Prepared:	February 18, 2026
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 (K230742)

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 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 hypertube 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 K230742.

Substantial Equivalence: The ACCLARENT AERA® Eustachian Tube Balloon Dilation System device has identical indications for use, labeling, and technological characteristics as the predicate device.

To meet special control 21 CFR 874.4180 (b)(6), simulated use cadaver training is offered to all clinicians. An updated training plan is provided, featuring additional alternative options, including leveraging previous ETBD system clinical experience and using a 3D printed head model in place of a cadaver model

Performance Data: Previously submitted performance data were leveraged, as the subject device is identical in design and performance specifications as compared to the predicate device.

Previously submitted data included:

- Bench testing demonstrating acceptance criteria was met for attributes such as dimensional specifications, cycle fatigue, balloon burst, and bond separation
- Biocompatibility testing
- Sterilization, shipping and stability testing

Additional simulated use testing was executed in support of this submission to demonstrate the suitability and equivalence of the proposed alternative training methods to meet special control 21 CFR 874.4180 (b)(6).

Design validation to support equivalence of the 3D printed head model to the cadaver model was conducted. The 3D printed model was based on CT scans of a real cadaver, and the materials were assessed to mimic tissue characteristics and anatomical geometry specific to ETBD procedures.

Validation was performed with four evaluators (ENT surgeons) with the PHACON Sinus and Eustachian Tube Model to ensure it was representative of ET anatomy and could be utilized as a surgical training tool for balloon dilation of the Eustachian tube. The surgeons had at least 3 years of eustachian tube balloon dilatation experience and had completed at least 50 cases. The study was conducted in the operating room or office treatment room.

The data collected from the four evaluators showed that the model was representative of Eustachian tube anatomy in color, feel, and contrast. All tasks for balloon dilation of the Eustachian tube were performed successfully, and all evaluators agreed the model was suitable for Eustachian tube balloon dilation (ETBD) training. The results demonstrated that the PHACON Sinus and Eustachian Tube Model has passed validation testing and was able to be used as a training tool for ETBD.

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 was leveraged to support safety and effectiveness compared to the predicate. Additional clinical testing was not required to support substantial equivalence. To meet special control 21 CFR 874.4180 (b)(6), simulated use cadaver training is offered to all clinicians. An updated training plan that includes leveraging of prior ETBD clinical experience and validation testing to support the use of a 3D printed head model as an alternative to a cadaver model, were provided to fulfil the special control of 21 CFR 874.4180(b)(6) for simulated use training on cadavers. The ACCLARENT AERA® Eustachian Tube Balloon Dilation System is substantially equivalent to the predicate.