April 12, 2022

Entellus Medical, Inc.
Katie Wilson
Sr. Staff, Regulatory Affairs Specialist
3600 Holly Lane North, Suite 40
Plymouth, Minnesota 55447

Re: K220027
Trade/Device Name: Audion ET dilation system
Regulation Number: 21 CFR 874.4180
Regulation Name: Eustachian Tube Balloon Dilation System
Regulatory Class: Class II
Product Code: PNZ
Dated: March16, 2022
Received: January 5, 2022

Dear Katie Wilson:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

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)*
K220027

Device Name
Audion ET dilation system

Indications for Use *(Describe)*

To dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in patients 18 years and older using a transnasal approach.

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

Date Prepared: December 31, 2021

Submitter Information:
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Establishment Registration: 3006345872

Contact Information:
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Device Information:

Trade Name:	Audion ET dilation system
Common Name:	Eustachian Tube Balloon Dilation Device
Classification Name:	Eustachian Tube Balloon Dilation Device
Product Code:	PNZ
Regulation Number:	Class II 21 CFR 874.4180
Predicate Devices:	K163509 XprESS ENT Dilation System

Device Description:

The Audion ET dilation system (ET is an abbreviation for Eustachian tube) is intended to dilate the Eustachian tube through use of balloon dilation and a transnasal approach. It contains a dilation device, inflation device and inflation lock. The dilation device has a 1.26 mm outer diameter (OD) curved non-malleable shaft with a balloon fixed at the distal end and a 1.91 mm atraumatic polymer ball tip. The dilation device is positioned under endoscopic visualization with the balloon fully retracted. Once the portion of the device from the ball tip to the base of the curve is seated in the Eustachian tube, the balloon is advanced and then inflated. The deployed balloon angle of the dilation device is 45° for optimal treatment of the Eustachian tubes. The distal leg length with balloon extended is 18.5 mm. When the balloon is inflated to 12 atm, the balloon diameter is 6mm and the body length is 20 mm.

The inflation device is an accessory that consists of an inflation syringe and an extension line. The inflation device is designed to deliver a pressure of 12 atm and is used to inflate the balloon on the dilation device.

The inflation lock is an optional accessory that is intended to interface with the Audion dilation device, inflation syringe and extension line connections to hold or release pressure during balloon dilation.

The Audion ET dilation system is provided sterile and is for single patient use only. The dilation device, inflation device and inflation lock are sterilized using ethylene oxide.

The Audion ET dilation system has been tested to withstand multiple inflations in a surgical case

Indications for Use:
To dilate the cartilaginous portion of the Eustachian Tube for treating persistent Eustachian Tube dysfunction in patients 18 years and older using a transnasal approach.

Contraindications:
There are not any known contraindications that directly refer to the product. The physician is responsible for deciding if the general condition of the patient allows the intended application.

Technological Characteristics:
The technological characteristics of the Audion ET dilation system are similar to the predicate device [K163509], including Principles of Operation, design, function, materials, biocompatibility, and sterility.

The Audion ET dilation system and its predicate [K163509] both:

- have the same intended use and indications for use with respect to Eustachian tube dilation
- use balloon technology with 12 atm of pressure to dilate Eustachian tube anatomy
- extend no more than 19.5 mm into the cartilaginous portion of the Eustachian tube and feature similar distal ball tip dimensions
- include the same inflation syringe and extension line
- are sterilized using ethylene oxide
- provided for single patient use only, and
- are for use by healthcare professionals (physicians) only

There are some minor design differences between the subject and predicate device:

- The subject Audion dilation device features a non-malleable shaft that cannot be reshaped and is only intended for Eustachian Tube dilation, while the predicate device [K163509] has a malleable shaft that may be reshaped and is intended to dilate both Eustachian tube and sinus anatomy.

- The subject device has a formed, atraumatic polymer ball tip while the predicate device [K163509] features an atraumatic stainless-steel ball tip. Unlike the predicate device [K163509], the Audion ET dilation system is not designed to accommodate the use of guidewires nor is it designed to allow for suction, irrigation or use of the LED Light Fiber.
- Audion ET dilation system includes an inflation lock for optional use

Substantial Equivalence:
The Audion ET dilation system has been shown to be substantially equivalent to the predicate device [K163509], based on Intended Use, Indications for Use, Principles of Operations and Technological Characteristics. The Intended Use and Indications for Use are identical to the predicate device's [K163509] Intended Use and Indications for Use with respect to Eustachian Tube balloon dilation. The main differences between the devices are that the predicate [K163509] has a malleable shaft that allows the predicate [K163509] to be configured for use in sinus anatomy and in the Eustachian tube while the subject device has a non-malleable shaft and is for use only in the Eustachian tube. Additionally, the predicate [K163509] has a stainless-steel ball tip while the subject device has a polymer ball tip.

While there are some minor design differences between the subject and predicate [K163509] devices, these differences do not raise different questions of safety or efficacy.

Performance Data:
Bench testing was performed to demonstrate that the Audion ET dilation system performs as intended and meets the design specification. The testing included biocompatibility, design verification (dimensional, functional, strength, HFE/UE verification testing), packaging, shelf life and design validation with ENT physicians (HFE/UE). Performance testing showed that the device meets design specifications and performs as intended.

Conclusion:
The Audion ET dilation system has been shown to be substantially equivalent to the predicate device based on Indication for Use, Intended Use, Principles of Operation and technological characteristics. The minor design differences between the subject device and the predicate device (e.g., update to a non-malleable shaft with polymer ball tip) do not raise different questions of safety or efficacy and performance testing has been conducted to demonstrate the Audion ET dilation system performs as intended and is substantially equivalent to the predicate device.