February 19, 2021

Exercore, LLC
% Lisa Pritchard
Regulatory, Quality & Compliance Consultant
DuVal & Associates, P.A.
825 Nicollet Mall, Suite 1840
Minneapolis, Minnesota 55402

Re: K203754
Trade/Device Name: Eustachi Ear Pressure Relief Device
Regulatory Class: Unclassified
Product Code: MJV
Dated: December 22, 2020
Received: December 23, 2020

Dear Lisa Pritchard:

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
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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)*
K203754

Device Name
Eustachi Ear Pressure Relief Device

Indications for Use *(Describe)*
The Eustachi is indicated for the treatment of negative middle ear pressure.

Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing, and hearing loss. The Eustachi provides a method of ventilating the middle ear by momentarily increasing the air pressure in the nose and the eustachian tube. Equalizing the pressure can prevent the accumulation of fluid and prevent hearing loss.

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."*

# 510(k) Summary - K203754

I. SUBMITTER

Exercore, LLC
8170 Old Carriage Court North, Suite 200
Minneapolis, MN 55379

Phone: 888-406-0668

Contact Person: Kevin Connelly
Date Prepared: February 16, 2021

II. DEVICE

Name of Device: Eustachi® Ear Pressure Relief Device
Common or Usual Name: Eustachi
Classification Name: Middle Ear Inflation Device
Regulatory Class: Unclassified
Product Code: MJV

III. PREDICATE DEVICE

EarPopper, K073401
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Eustachi device is a battery-operated device designed to blow a controlled flow of air into the nose to facilitate opening the eustachian tubes. For use, the nosepiece is fitted tightly against one nostril to make an airtight seal. While pinching the other nostril shut, the Eustachi device is activated by pressing and holding the power button. The patient swallows while the device is running, allowing regulated air to move from the nose to the eustachian tube to help open the eustachian tube and equalize pressure in the middle ear.

Eustachi is provided non-sterile, and is designed for reuse with a single patient.

## V. INDICATIONS FOR USE

The Eustachi is indicated for the treatment of negative middle ear pressure.

Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing, and hearing loss. The Eustachi provides a method of ventilating the middle ear by momentarily increasing the air pressure in the nose and the eustachian tube. Equalizing the pressure can prevent the accumulation of fluid and prevent hearing loss.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject and predicate devices are designed for user by patients to relieve negative middle ear pressure. Both devices create a flow of air into the nose to eustachian tube, delivered at a specified pressure and volume. Both require the patient to swallow during use to facilitate movement of air into the eustachian tube. At a high level, the subject and predicate devices are based on equivalent technological characteristics as shown in Table 1. Validation from non-clinical testing and usability evaluation demonstrated that minor differences in technological characteristics do not raise any new questions of safety or effectiveness.

*Table 1: Comparison of Technological Characteristics*

| **Item** | **Subject Device**<br>**Eustachi** | **Primary Predicate Device**<br>**K073401**<br>**EarPopper** |
|---|---|---|
| Intended Use | Treatment of negative middle ear pressure | Treatment of negative middle ear pressure |
| Indications for Use | The Eustachi is indicated for the treatment of negative middle ear pressure.<br><br>Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing, and hearing loss. The Eustachi provides a method of ventilating the middle ear by momentarily increasing the air pressure in the nose and the eustachian tube. Equalizing the pressure can | The EarPopper is indicated for the treatment of negative middle ear pressure.<br><br>Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing, and hearing loss. The EarPopper provides a method of ventilating the middle ear by momentarily increasing the air pressure in the nose and the eustachian tube. Equalizing the pressure can prevent the |

| Item | Subject Device<br>Eustachi | Primary Predicate Device<br>K073401<br>EarPopper |
|---|---|---|
| | prevent the accumulation of fluid and prevent hearing loss. | accumulation of fluid and prevent hearing loss. |
| Type of Use | Over-the-Counter | Prescription Use |
| Patient Use | Performed at home by patient on their own or under adult supervision | Performed at home by patient on their own or under adult supervision |
| Intended Use Environment | Home Use | Home Use |
| Components | Handheld unit | Handheld unit |
| Mechanism of Action | Provides flow of air to open eustachian tube | Provides flow of air to open eustachian tube |
| Patient Contact Type | Surface-contact device in contact with mucosal tissue for limited duration | Surface-contact device in contact with mucosal tissue for limited duration |
| User Interface | Single button press on handheld unit | Single button press on handheld unit |
| Air Pressure | 31 – 41 kPa (4.5 to 6 PSI) | 3 – 6 PSI |
| Air Flow Rate | 1.7 – 2.1 LPM | 0.6 – 1.3 LPM |
| Power Supply | Alkaline Battery-powered (2 AA) | Alkaline Battery-powered (9V) |
| Sterility | Non-sterile | Non-sterile |

## VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

**Biocompatibility Testing**

The biocompatibility evaluation of the Eustachi device was conducted in accordance with ISO 10993-1: 2018 (FDA recognition # 2-258) and FDA guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," issued June 16, 2018. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation / Intracutaneous reactivity

The Eustachi nosepiece (ABS plastic) is considered to be a surface-contact device in contact with mucosal tissue for limited cumulative duration (less than 24 hours).

**Cleaning Validation**
Cleaning validation was conducted in accordance with AAMI TIR30:2011/(R)2016 to validate effectiveness of the Eustachi cleaning instructions.

**Electrical Safety and Electromagnetic Compatibility (EMC)**
Electrical safety and EMC testing were conducted on the Eustachi device. The device complies with applicable sections of IEC 60601-1: 2012 and IEC 60601-1-11: 2015 standards for electrical safety, and IEC 60601-1-2 edition 4 for EMC.

**Bench Testing**
Bench testing was conducted to validate intended performance of the Eustachi device including dimensional verification, pressure value verification, flow rate verification, and drop test verification.

**Usability Testing**
A study was conducted in accordance with IEC 62366-1: 2016 and IEC 60601-1-6: 2013 to verify the ability of potential users to complete the following tasks when no training is provided to simulate over-the-counter home use:

- Identify whether the device would be appropriate for them to use;
- Understand and complete the tasks required for use of the device;
- Understand when a healthcare professional should be consulted

**Software Verification and Validation**
The Eustachi does not contain software; no software verification or validation was required.

**Animal Performance Study**
No animal performance studies were required for the Eustachi device.

**Clinical Study**
No clinical studies were required for the Eustachi device.

## VIII. CONCLUSIONS

The biocompatibility, electrical safety, EMC, and bench testing conducted provide evidence that the Eustachi performs comparable to the predicate device. The Eustachi has the same intended use as the predicate device. The usability testing conducted provides evidence that the Eustachi labeling is sufficient to support over-the-counter (OTC) use by ensuring the device performs safely when used by lay users with no previous training. The data

provided supports substantial equivalence of the Eustachi to the predicate device.