June 9, 2023

Ningbo Albert Novosino Co., Ltd.
% Doris Dong
General manager
Shanghai CV Technology Co., Ltd.
Room 903, No.19 Dongbao Road, Songjiang Area,
Shanghai, Shanghai 201613
China

Re: K230502
Trade/Device Name: Ear Pressure Relief Device (ER813B)
Regulatory Class: Unclassified
Product Code: MJV
Dated: May 10, 2023
Received: May 12, 2023

Dear Doris Dong:

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,

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

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)*

Device Name
Ear Pressure Relief Device

Indications for Use *(Describe)*
The Ear Pressure Relief Device 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 Ear Pressure Reliever 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.

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510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K230502
Date:	June 8, 2023
Type of 510(k) Submission:	Traditional 510(k)
Basis for 510(k) Submission:	New device
Owner:	Ningbo Albert Novosino Co.,Ltd. No. 28 Yunshan Middle Road, Sanqishi town, Yuyao, Zhejiang 315412, China Contact person:Victor Zhou Tel: 86-574-87527882 Email: victor@albertnovosino.com
Contact:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 602, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description

Proprietary Name:	Ear Pressure Relief Device
Model:	ER813B
Common Name:	Middle Ear Inflation Device
Classification Name:	Device, Inflation, Middle Ear
Product Code:	MJV
Device Class:	Unclassified
Review Panel:	Ear Nose & Throat
Device Description:	The Ear Pressure Relief Device is 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 Ear Pressure Relief Device is activated by pressing and holding the adjustment 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. Ear Pressure Relief Device is provided non-sterile, and is designed for reuse with a single patient.
Indications for use:	The Ear Pressure Relief Device 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 Ear Pressure Relief Device 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.

3. Predicate Device Information

Predicate 510(k) Number: K203754
Marketing clearance date: 02/19/2021
Product name: Eustachi Ear Pressure Relief Device
Manufacturer: Exercore, LLC

4. Comparison to predicate device

Parameters	**New Device**	**Predicate Device**	**Comparison**
510(k) number	K230502	K203754	--
Submitter	Ningbo Albert Novosino Co.,Ltd.	Exercore, LLC	--
Device name	Ear Pressure Relief Device	Eustachi Ear Pressure Relief Device	--
Model	ER813B	/	--
Device class	Unclassified	Unclassified	Same
Product code	MJV	MJV	Same
Classification name	Device, Inflation, Middle Ear	Device, Inflation, Middle Ear	Same
Indications for use	The Ear Pressure Relief Device 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 Ear Pressure Relief Device 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.	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.	Same
Type of Use	Over-the-Counter	Over-the-Counter	Same
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	Same
Intended Use Environment	Home Use	Home Use	Same
Sterile	Non-Sterile	Non-Sterile	Same
Product Dimension(mm) [H*W*D]	152.3*35.5*29.7mm	155*30*45mm	Similar Note 1
Product Weight	105g	116.4g	
Output Head	One output head	One output head	Similar

	Diameter:16mm	Diameter:22mm	Note 3
Components	Handheld unit	Handheld unit	Same
Power Supply	Lithium battery	Alkaline Battery-powered (2 AA)	Similar Note 2
Mechanism of Action	Provides flow of air to open eustachian tube	Provides flow of air to open eustachian tube	Same
User Interface	Press on power button,then press on working button	Single button press on handheld unit	Similar Note 1
Air Pressure	31 – 41 kPa (4.5 to 6 PSI)	31 – 41 kPa (4.5 to 6 PSI)	Same
Air Flow Rate	1.7 – 2.1 LPM	1.7 – 2.1 LPM	
Patient Contact Type	Surface-contact device in contact with mucosal tissue for limited duration (less than 24 hours)	Surface-contact device in contact with mucosal tissue for limited duration (less than 24 hours)	Same
Materials	ABS plastic	ABS plastic	Same
Labeling	Meet FDA's requirement	Meet FDA's requirement	Same

Differences between New device and Predicate Device:

Note 1:

The weight, dimensions and user Interface of the proposed device are a little different from the predicate device, this is a slightly different product design, but these differences are minor and do not affect device performance as compared to the predicate device.

Note 2:

The power supply of the proposed device are a little different from the predicate device,but these differences are insignificant in terms of safety or effectiveness.In addition, the proposed device has passed the electrical safety test and ,so these differences don't raise any new safety and effectiveness issues.

Note 3:

The predicate device requests that the user to press the nosepiece tightly against one nostril making an airtight seal and pinch other nostril tightly shut with other hand making an airtight seal.While the subject device requires the user to press the silicone heads tightly into both nostrils and ensure air tightness.The only difference is that instead of using hand to seal the other nostril, the new device uses its own silicon head.We have studied the diameter of nasal products on the market from 5 to 12 mm, and the diameter of the output head of both the new device and the predicate device can cover this range.In order to prove the same sealing effect, we did an additional air tightness test with the silicon head.

In addition, we have added in the instruction manual that users can use hand instead of silicone head to block the other nostril during treatment, depending on their personal habits.Therefore, we believe that this difference will not affect the device performance as compared to the predicate device.

5. Non-clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate devices. The test results demonstrated that the proposed device complies with the following standards:

Electrical safety and electromagnetic compatibility (EMC):

1) ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD);

2) IEC 60601-1-2:2014, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests;

3) IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Biocompatibility testing:

The biocompatibility evaluation for the Ear Pressure Relief Device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. A series of tests include the following tests:

1) ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

2) ISO 10993-10Third Edition 2021-11, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

3) ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation.

Bench Testing:

Bench testing was conducted to validate intended performance of the Ear Pressure Relief Device:

a. Dimensional verification
b. Pressure value verification
c. Flow rate verification
d. Drop test verification

Software Verification and Validation Testing:

This product does not include software.

6. Animal Study

Animal testing was not required for this submission.

7. Clinical Testing

Clinical testing was not required for this submission.

8. **Conclusion**

The biocompatibility, electrical safety, EMC, and bench testing conducted provide evidence that the proposed device performs comparable to the predicate device. The conclusions drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as the predicate device.