



February 10, 2026

Earflo Inc.
Roxanne Dubois
Regulatory Consultant
584 Rio Del Mar Blvd
Aptos, California 95003

Re: K252751

Trade/Device Name: Earflo (EF001)
Regulatory Class: Unclassified
Product Code: MJV
Dated: December 12, 2025
Received: December 12, 2025

Dear Roxanne Dubois:

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 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 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,

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

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.

K252751

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Please provide the device trade name(s).

?

Earflo (EF001)

Please provide your Indications for Use below.

?

The Earflo 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 Earflo 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.

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

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

?

Premarket Notification 510(k) Summary

510(k) Owner:	Earflo Inc., 203 Lothrop Street, St#500, Pittsburgh, PA 15213, USA
Company Contact Person:	Intan Oldakowska, intan@earflo.com ; T: 01161431867417
Submission Correspondent:	Roxanne Dubois, rduboisconsulting@gmail.com ; T: 408-828-5019
Date Summary Prepared:	February 10, 2026
Trade Name (Model No.):	Earflo (Model EF001)
Common Name:	Middle Ear Inflation Device
Classification & Regulation:	Class II and Unclassified
Product Code & Panel:	MJV; Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1), Division of Dental and ENT Devices (DHT1B); Ear Nose & Throat Panel
Primary Predicate Device:	Ear Pressure Relief Device, K230502, Code MJV
Reference Device:	Eustachi Ear Pressure Relief Device, K203754, Code MJV

A. Device Description

Earflo is a rechargeable, hand-held therapeutic device designed to provide treatment of negative middle ear pressure through a non-invasive method. Earflo functions by delivering controlled pressurized air into the nasal passages to ventilate the middle ear by momentarily increasing the air pressure in the nose and eustachian tubes. During use, the child drinks from the integrated sippy cup while the nose is sealed against the device's mask. When liquid is swallowed, a puff of air is delivered into the nasal passage and eustachian tube, thereby opening the eustachian tube and equalizing pressure in the middle ear. Earflo is intended for use in children aged two years and older (under adult supervision) and adults to relieve negative middle ear pressure, prevent the accumulation of middle ear fluid, and prevent hearing loss.

B. Indications for Use

The Earflo 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 Earflo 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.

C. Technological Characteristics

Earflo is an over-the-counter, reusable, non-sterile medical device intended to equalize middle ear pressure through controlled nasal air flow synchronized with swallowing. Earflo consists of an electronic base with a microcontroller-driven pump, a sippy-cup style assembly, interchangeable nasal masks, and an optional Bluetooth-enabled companion mobile App that provides gamified feedback.

The difference in the subject device's physical dimensions includes an integrated sippy-cup style assembly that enables treatment to be delivered naturally during swallowing.

The subject device includes interchangeable interface options to accommodate patient anatomical variations, and to improve comfort and fit during treatment. Device masks were evaluated during bench testing to ensure consistent air flow delivery and pressure profiles. The interchangeable interface design provides flexibility to adapt to different user preferences.

D. Performance Testing

Nonclinical verification and validation performance testing included electrical safety and EMC, air pressure and air flow rate testing, software verification, packaging and transportation, usability and biocompatibility testing.

The subject device was designed to deliver a lower maximum pressure to reduce the risk of nasal discomfort and to ensure tolerability. The lower pressure range is within clinically effective limits for achieving eustachian tube opening as validated through bench testing. The air pressure testing demonstrated that pressure delivery was controlled and repeatable within the defined operating range.

The difference in maximum airflow rate is transient when the user is swallowing, and the airflow rate when they are not swallowing is less than the predicate device. The increased airflow rate during swallowing allows the device to seal more reliably. Bench testing demonstrated that nominal operating flow is substantially equivalent to the predicate.

Test results confirmed that Earflo met design specifications, safety requirements, and relevant consensus standards, including performance, electrical safety and EMC, air pressure and air flow rate testing, software verification, packaging and transportation, usability and biocompatibility. The nonclinical data provides reasonable assurance of safety and effectiveness and supports substantial equivalence to the predicate.

E. Basis of Substantial Equivalence

The subject and predicate devices have the same intended use, indication for use, and similar technological characteristics, materials of construction, principles of operation, design features and characteristics.

The conclusions drawn from the performance testing demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device. It is determined that the subject and predicate devices are substantially equivalent.