June 2, 2026

FindAir Sp. z o.o.
% Oliver Eikenberg
Global QA/RA Manager
Pure Global
11 Town Square Place, Suite 1203
Jersey City, New Jersey 07310

Re: K260270
Trade/Device Name: FindAir ONE for pMDI (FAO-MDI-V12-GRE-001)
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: April 29, 2026
Received: April 29, 2026

Dear Oliver Eikenberg:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assitant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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.	K260270

Please provide the device trade name(s).

FindAir ONE for pMDI (FAO-MDI-V12-GRE-001)

Please provide your Indications for Use below.

The purpose of FindAir ONE for pMDI FOMDI10 is to collect information on the use of the pMDI to support the inhalation therapy of targeted respiratory diseases. The product is aimed at patients and professionals (physicians, researchers) who wish to collect data on the use of inhalers. The FindAir ONE for pMDI FOMDI10 may also be used to send data to remote therapeutic monitoring systems (RTM).
The product is intended for adult patients and people under adult care (both children older than 2 years of age and adults requiring supervision). The product is intended for multiple use by single user. Up to 127 uses of the inhaler can be recorded and stored in FindAir ONE for pMDI FOMDI10.
FindAir ONE for pMDI FOMDI10 can be used in indoor and outdoor settings such as at home, at work, in the environment of specialist clinics, etc.
The product is not intended for diagnosis or treatment and does not replace diagnosis by a doctor or treatment prescribed by a doctor.
The FindAir ONE for pMDI FOMDI10 device complies with the requirements of IEC 60601-1 as a product with a type BF applied part.
The app, FindAir Viewer, is designed for iOS and Android (mobile only), enabling:
- Connection to the FindAir ONE for pMDI FOMDI10 device
- Reading data from the FindAir ONE for FOMDI10 devices (battery status, number of stored events, total number of clicks, total operating time, MAC address).
- Presentation of this data in an easy-to-read form to the user.
- Warning of low battery status
- Transmits usage events from device

The FindAir Viewer application will be made available to users via the Apple App Store and Google Play, It is intended to be used exclusively with the FindAir ONE for pMDI FOMDI10 device and is provided to customers as part of the product package.
Designed for single-patient use, it assists professionals (physicians, researchers) and patients in documenting and monitoring the use of their prescribed pMDI device.
Parameters of the metal canister compatible with FindAir ONE for pMDI FOMDI10:
• External shape of the canister: round
• Minimum canister diameter: 20.5 mm
• Maximum canister diameter: 23.5 mm
• Protruding above the housing by at least 7 mm

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 (traditional)

FindAir ONE for pMDI FOMDI10

K260270

1. **Date Prepared:** 01 June 2026

2. **510(k) Owner / Applicant Submission Sponsor**
   FindAir Sp. z o.o.
   Glogowa 26
   30-394 Kraków, POLAND
   Contact: Anna Pawlik, Quality Management Representative

3. **Submission Correspondent**
   Pure Vision AI, Inc (dba Pure Global)
   111 Town Square Place, Suite 1203
   Jersey City, NJ 07310, USA
   Contact: Oliver Eikenberg, PhD , Senior Consultant, Global Quality & Regulatory Affairs Manager

4. **Device Identification**
   Trade/Proprietary Name(s): FindAir ONE for pMDI FOMDI10
   Common/Usual Name: FindAir ONE for pMDI
   Classification Name: Nebulizer
   Regulation number: 21 CFR 868.5630
   Product Code: CAF - Nebulizer (Direct Patient Interface)
   Device Class: Class II
   Classification Panel: Anesthesiology

5. **Legally Marketed Predicate Device**

   K223367, Ochsner Connected Inhaler Sensor, Ochsner Clinic Foundation, New Orleans, LA, USA

6. **Device Description**
   The FindAir ONE for pMDI FOMDI10 is an electronic accessory device for pressurized metered dose inhalers (pMDIs). The device is mounted on the top of the inhaler canister. It is mechanically pressed whenever the patient uses the inhaler to deliver the medicine contained in the inhaler. Simple operation of the device allows the patient to use the product independently. The pressing of FindAir ONE for pMDI FOMDI10 activates the electronic sensor inside the device enclosure. FindAir ONE for pMDI FOMDI10 records the use of the inhaler. This data is stored in the FindAir ONE for pMDI FOMDI10. The FindAir ONE for pMDI FOMDI10 is able to connect via Bluetooth to software (FindAir Viewer) on compatible mobile devices, tablets of choice to download data from

the FindAir ONE for pMDI FOMDI10, and allow it to be viewed and sent to appropriate databases. When there is no connection to the device via Bluetooth data collection device, it is possible to make and store up to 127 usable records available in FindAir ONE for pMDI FOMDI10 (maximum capacity). Data above 127 records is overwritten by the logic first in first out.

FindAir ONE for pMDI FOMDI10 fits pMDI canisters with dimensions between 20.5 - 23.5 mm in diameter, extending above the case by at least 7 mm, regardless of the medication contained in it.

7. Intended Use/Indication for Use Statement

The purpose of FindAir ONE for pMDI FOMDI10 is to collect information on the use of the pMDI to support the inhalation therapy of targeted respiratory diseases. The product is aimed at patients and professionals (physicians, researchers) who wish to collect data on the use of inhalers. The FindAir ONE for pMDI FOMDI10 may also be used to send data to remote therapeutic monitoring systems (RTM).

The product is intended for adult patients and people under adult care (both children older than 2 years of age and adults requiring supervision). The product is intended for multiple use by single user. Up to 127 uses of the inhaler can be recorded and stored in FindAir ONE for pMDI FOMDI10.

FindAir ONE for pMDI FOMDI10 can be used in indoor and outdoor settings such as at home, at work, in the environment of specialist clinics, etc.

The product is not intended for diagnosis or treatment and does not replace diagnosis by a doctor or treatment prescribed by a doctor. The FindAir ONE for pMDI FOMDI10 device complies with the requirements of IEC 60601-1 as a product with a type BF applied part.

The app, FindAir Viewer, is designed for iOS and Android (mobile only), enabling:

- Connection to the FindAir ONE Device
- Reading data from the FindAir ONE Devices (battery status, number of stored events, total number of clicks, total operating time, MAC address).
- Presentation of this data in an easy-to-read form to the user.
- Warning of low battery status
- Transmits usage events from device

The FindAir Viewer application will be made available to users via the Apple App Store and Google Play. It is intended to be used exclusively with the FindAir ONE for pMDI device and is provided to customers as part of the product package.

Designed for single-patient use, it assists professionals (physicians, researchers) and patients in documenting and monitoring the use of their prescribed pMDI device. Parameters of the metal canister compatible with FindAir ONE for pMDI FOMDI10:

- External shape of the canister: round
- Minimum canister diameter: 20.5 mm
- Maximum canister diameter: 23.5 mm
- Protruding above the housing by at least 7 mm

8. Comparative Summary of Substantial Equivalence - Discussion of Similarities and Differences

Table – Comparison of Characteristics between Subject Device and Predicate Device

	Predicate Device (K223367)	**Subject Device**
Trade Name	**Ochsner Connected Inhaler Sensor**	**FindAir ONE for pMDI FOMDI10**
Device Type	Electronic accessory device for inhalers	
Product Code	CAF Nebulizer (direct patient interface)	
Regulation Number	868.5630 Nebulizer	
Indications for Use	The Ochsner Connected Inhaler Sensor System includes the Ochsner Connected Inhaler Sensor. The Sensor is an accessory device intended for single-patient use to assist physicians and patients in recording and monitoring actuations of prescribed MDI usage. The Ochsner Connected Inhaler Sensor Mobile Application records, stores, and transmits usage events from the Sensors to a remote storage system. Users can review information collected from the Sensors and share it with caregivers, physicians, and healthcare providers. When used with a prescribed MDI, the system can report information captured during normal use, such as the time between actuations, which can help assess inhaler technique. The system is intended for populations from children (>2 years) to adults and may be used indoors and outdoors including home, work, clinical settings, and during clinical trials. The output of the system is not intended to diagnose or replace a diagnosis provided by a physician and is not intended to function as an inhaler dose counter.	The purpose of FindAir ONE for pMDI FOMDI10 is to collect information on the use of the pMDI to support the inhalation therapy of targeted respiratory diseases. The product is aimed at patients and professionals (physicians, researchers) who wish to collect data on the use of inhalers. The FindAir ONE for pMDI FOMDI10 may also be used to send data to remote therapeutic monitoring systems (RTM). The product is intended for adult patients and people under adult care (both children older than 2 years of age and adults requiring supervision). The product is intended for multiple use by single user. Up to 127 uses of the inhaler can be recorded and stored in FindAir ONE for pMDI FOMDI10. FindAir ONE for pMDI FOMDI10 can be used in indoor and outdoor settings such as at home, at work, in the environment of specialist clinics, etc. The product is not intended for diagnosis or treatment and does not replace diagnosis by a doctor or treatment prescribed by a doctor. The FindAir ONE for pMDI FOMDI10 device complies with the requirements of IEC 60601-1 as a product with a type BF applied part. The app, FindAir Viewer, is designed for iOS and Android (mobile only), enabling: • Connection to the FindAir ONE Device • Reading data from the FindAir ONE Devices (battery status, number of stored events, total number of clicks, total operating time, MAC address). • Presentation of this data in an easy-to-read form to the user. • Warning of low battery status • Transmits usage events from device The FindAir Viewer application will be made available to users via the Apple App Store and Google Play. It is intended to be used exclusively with the FindAir ONE for

	Predicate Device (K223367)	Subject Device
Trade Name	**Ochsner Connected Inhaler Sensor**	**FindAir ONE for pMDI FOMDI10**
		pMDI device and is provided to customers as part of the product package. Indications for use Designed for single-patient use, it assists professionals (physicians, researchers) and patients in documenting and monitoring the use of their prescribed pMDI device. Parameters of the metal canister compatible with FindAir ONE for pMDI FOMDI10 I: • External shape of the canister: round • Minimum canister diameter: 20.5 mm • Maximum canister diameter: 23.5 mm • Protruding above the housing by at least 7 mm
Characteristics	Compact device suitable for single-patient use, Operates on a non-rechargeable battery	
Sensors and Mechanism	Mechanical actuation button detects inhaler use and logs time and duration of actuation events in device memory	Mechanical pressure sensor activates with each use of the inhaler and logs time and usage.
Design – Attachment to Medication Dispenser	Physically attached to dispenser without inhibiting patient use	Physically attached to dispenser without inhibiting patient use. List of compatible drugs can be found in the IFU.
Keyboard/Input Interface	Single button interface	
Data Collection	Records the date and time of MDI usage when actuation occurs and stores this information in internal memory until synchronized with the mobile application	Records each inhaler actuation; can connect to a mobile application via Bluetooth protocol to upload usage data Stores logs up in internal memory. Records the date and time of pMDI usage by monitoring the actuation of the pMDI
Communication Protocol	Bluetooth Low Energy (BLE) wireless communication with a mobile application.	Bluetooth Low Energy (BLE) – enables wireless data transfer to compatible mobile applications (connects in Advertising and Connected modes)
Power Source	CR2032 coin battery	CR2032 coin battery
Low battery indicator	Yes, light combination; software display of battery life.	Software display of battery life.
Material - Patient Contact by Intact Skin	Silicone rubber external enclosure	ABS polymer, Thermoplastic Elastomer (TPE), Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS)

	Predicate Device（K223367)	Subject Device
Trade Name	**Ochsner Connected Inhaler Sensor**	**FindAir ONE for pMDI FOMDI10**
Durability and Use Scenario	Durable materials for medical use, implied capability to endure regular patient handling	Material composition selected to endure daily handling in a medical environment (e.g., exposure to skin, environmental factors), resistant to physical impact
User Setup Requirements	Attaches to the inhaler by the user; simple attachment without complex orientation. Bluetooth pairing required for data transfer	Attaches to the inhaler by the user; simple attachment without complex orientation. Bluetooth connecting required for data transfer
Patient Interaction	Easy setup and attachment to the inhaler. Inhaler actuations are automatically recorded and synchronized with the mobile application	Easy attachment and intuitive usage. Users need to attach, activate, and ensure the device syncs data through mobile app
Indication of Device Status	No on-device visual feedback for inhaler actuation detection and recording	LED light feedback on the device shows successful activation and recording
Operating System	● iOS version 14 or higher ● Android operating system version 11 or higher	● iOS versions 15 or higher ● Android operating system 8 or higher
Required Browser	No	No
Required Off the Shelf Hardware	● Apple smartphones or devices with Bluetooth, iOS 14 or higher ● Android smartphones or devices with Bluetooth and operating system version 11 or higher	● Apple smartphones with iOS versions 15 or higher and Bluetooth BLE 4.0+ ● Android smartphones with operating system 8 or higher and Bluetooth BLE 4.0+
Mobile Application	The Ochsner Connected Inhaler Sensor Mobile Application records, stores, and transmits usage events from the sensor via smartphone and allows users to review inhaler usage information and share it with healthcare providers.	The FindAir Viewer Application collect, display, and communicate information from the FindAir ONE for pMDI device.
Software	The Ochsner Connected Inhaler Sensor system uses a mobile application to record, store, and display inhaler usage data and allows sharing of information with healthcare providers.	The FindAir Viewer Application is software intended to allow users to display information and characteristics of pMDI use.
Electrical Safety	IEC 60601 series standards	EN 60601-1-2:2015/A1:2021
Usability engineering	No information	IEC 62366-1:2015+A1:2020
Biocompatibility	ISO 10993 series standards	ISO 10993 series standards
Sterility	Non-sterile	Non-sterile

9. Technology Comparison

FindAir ONE for pMDI FOMDI10 and the predicate **Ochsner Connected Inhaler Sensor are both devices which use** mobile applications to allow the user to display information of pMDI use. FindAir ONE for pMDI FOMDI10 differs only in minor design and functions:

- Made out of different material, which has been tested for biocompatibility
- Has a visual LED feedback on the device to indicate inhaler actuation detection, while the predicate device does not provide on-device visual feedback for this function.
- Supports more recent versions of mobile platforms (smartphones)
- The candidate device mobile application does not include the functionality to share inhaler usage information with healthcare providers, while the predicate device mobile application allows users to share this data with healthcare providers.

The technology differences are minor between the subject device FindAir ONE for pMDI FOMDI10 and predicate device Ochsner Connected Inhaler Sensor. The conducted bench testing confirms that the FindAir ONE for pMDI FOMDI10 does not raise questions on safety or effectiveness and is substantially equivalent to the predicate device.

10. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of FindAir ONE for pMDI FOMDI10 and in showing substantial equivalence to the predicate device that is subject to this 510(k) submission, the following non-clinical performance tests have been conducted:

- Biocompatibility evaluation per ISO 10993-1 and testing for ISO 10993-5, ISO 10993-10, EN ISO 10993-23 to demonstrate that there is no direct patient-contacting materials
- Electrical safety testing per ANSI/AAMI ES 60601-1, IEC 60601-1-6, IEC 60601-1-11
- Electromagnetic Compatibility testing per IEC 60601-1-2
- Software verification and validation testing including system compatibility testing, risk analysis per IEC 62304/FDA Guidance
- Usability engineering testing per IEC 62366-1
- Risk Management per EN ISO 14971; all requirements were met and risks reduced as far as possible.

11. Statement of Substantial Equivalence

The minor differences between the FindAir ONE for pMDI FOMDI10 and the predicate device Ochsner Connected Inhaler Sensor do not raise new or different questions of safety and effectiveness. Technical product characteristics, performance testing and compliance with voluntary standards demonstrate that the FindAir ONE for pMDI FOMDI10 is substantially equivalent to the predicate device in terms of design, function, components, materials, principals of operation, performance characteristics, and intended use/indication.