October 16, 2024

% Eric Bannon
Vice President of Regulatory and Clinical Affairs
AlvaMed, Inc.
1116 Great Plain Avenue, Suite 1
Needham, Massachusetts 02495

Re: K240114
Trade/Device Name: UltraEzAir® (UEA1A)
Regulation Number: 21 CFR 868.5170
Regulation Name: Laryngotracheal Topical Anesthesia Applicator
Regulatory Class: Class II
Product Code: CCT
Dated: September 13, 2024
Received: September 13, 2024

Dear Eric Bannon:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant 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

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)*
K240114

Device Name

UltraEzAir® (UEA1A)

Indications for Use *(Describe)*

The UltraEzAir® is a topical anesthesia applicator used to apply topical anesthetic to a patient's oropharynx and upper airway region through the working channel of a flexible nasal laryngoscope using air flow. The device is designed for and intended to be used by physicians trained and experienced in flexible endoscopic techniques for elective outpatient procedures.

The safety and effectiveness of this device for use in the performance of topical anesthesia of the lower airways (below the level of the trachea) have not been established.

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.

510(k) Summary

1.1 Name and Address of Submitter

DUALAMS, Inc., dba AIRKOR®
7139 Azalea Lane
Dallas, Texas 75081
John Reid
President
Phone: +1 (972) 327 3345
johnfreid@airkor.com

1.2 Correspondent/Primary Contact Person

Eric Bannon
Vice President of Regulatory and Clinical Affairs
AlvaMed, Inc.
ebannon@alvamed.com
Phone: +1 (781) 710-8243
Fax: +1 (617) 249-0955

1.3 Submission Information

Date Summary Prepared:		October 16, 2024
Subject Device:	Trade/Device Name:	UltraEzAir®
	Manufacturer:	Airkor®
	Common Name:	Laryngotracheal topical anesthesia applicator
	Regulation Number:	21 CFR 868.5170
	Regulation Name:	Laryngotracheal topical anesthesia applicator
	Regulation Class	Class II
	Product Code:	CCT - Applicator (Laryngo-Tracheal), Topical Anesthesia
	Review Panel:	Anesthesiology
Predicate Device:	Clearance:	K153470 dated August 19, 2016
	Trade/Device Name:	MADgic Laryngo-Tracheal Mucosal Atomization Device
	Manufacturer:	TELEFLEX MEDICAL
	Regulation Number:	21 CFR 868.5170

	Regulation Name:	Laryngotracheal topical anesthesia applicator
	Regulation Class	Class II
	Product Code:	CCT - Applicator (Laryngo-Tracheal), Topical Anesthesia
Reference Device:	Clearance:	K201167 dated December 3, 2020
	Trade/Device Name:	AireHealth™ Nebulizer
	Manufacturer:	AireHealth Inc.
	Regulation Number:	21 CFR 868.5630
	Regulation Name:	Nebulizer
	Regulation Class	Class II
	Product Code:	CAF Nebulizer (Direct Patient Interface)

Valid Predicate Discussion

MADgic Laryngo-Tracheal Mucosal Atomization Device was selected as the valid predicate device used to support the 510(k) submission because it was cleared using well-established methods. The predicate device meets the expected predicate performance due to its duration of use. After conducting a search on the Manufacturer and User Facility Device Experience (MAUDE) Database, Medical Device Reporting (MDR), MedSun Reports Database, Medical Device Safety and CBER Safety & Availability (Biologics) and Recall Database websites it was found that there are no known unmitigated use-related or design safety issues and the predicate device has not been subject to a design-related recall.

Valid Predicate Device	A - Well established methods	B - Meets or exceeds expected predicate performance	C - Unmitigated use-related or design-related safety issues	D – Associated design-related recall
MADgic Laryngo-Tracheal Mucosal Atomization Device	Used relevant methods that were published in the public domain	History of safe use, established due to duration of device on the market	No known unmitigated use-related or design related safety issues	No design-related recall identified

1.4 Device Description

The UltraEzAir® is a prescription medical device intended for application of nebulized 4% topical lidocaine solution to the oropharynx and upper airway region of patients. The subject device is an electrically driven device. The subject device is intended to be used only in an outpatient clinical facility or office for anesthetic procedures by a healthcare professional who is trained by Airkor® on its use.

The UltraEzAir® is intended to be used on adult patients, weighing at least 80 lbs. requiring topical anesthesia of oropharynx and upper airway region prior to endoscopic examination in an outpatient clinical facility or office.

The UltraEzAir® consists of a reusable Base, a single-use non-sterile Mist Assembly placed on the Base, and a single-use nonsterile Delivery Line connected to the Mist Assembly. The Delivery Line is then connected to the working channel of an Olympus or Pentax flexible nasal laryngoscope and the lidocaine mist is applied using the distal end of the attached laryngoscope to adjacent target tissue. The application process is visualized using the attached laryngoscope.

1.5 Indications for Use

The UltraEzAir® is a topical anesthesia applicator used to apply topical anesthetic to a patient's oropharynx and upper airway region through the working channel of a flexible nasal laryngoscope using air flow. The device is designed for and intended to be used by physicians trained and experienced in flexible endoscopic techniques for elective outpatient procedures.

The safety and effectiveness of this device for use in the performance of topical anesthesia of the lower airways (below the level of the trachea) have not been established.

1.6 Summary of Technological Characteristics

The principle of operation is the same as the primary predicate device: the subject device is a topical anesthetic applicator. Both devices use tubing for the delivery of the anesthetic solution to the same mucosal membrane target region. For both the subject and the predicate devices, anesthetic solution is sprayed on the intended patient anatomy. The subject device mist of lidocaine solution is generated in the Mist Assembly, using piezoelectric nebulizer technology. The built-in air pump of the UltraEzAir® pushes the lidocaine mist out of the Mist Assembly, to be applied to the target. Users have three lidocaine mist delivery rates to choose from. The UltraEzAir® is equipped with a safety timer, which stops the generation of mist at 9 minutes of continuous use, and a temperature sensor and indicator, which also stops operation to prevent thermal damage to the internal components.

The following table provides an overview of general technological characteristics in comparison to the predicate and reference devices. Any differences in the technological characteristics are minor and reflect market strategy and/or perceived user preferences and do not impact the safety, effectiveness, or substantial equivalence of the device. Biocompatibility evaluation testing, reprocessing method evaluation, and performance testing have been performed on the subject device in order to establish substantial equivalence to the predicate devices.

Substantial Equivalence Comparison Table

Device	Subject Device	Predicate Device	Reference Device
Trade Name	UltraEzAir	MADgic™ LaryngoTracheal Mucosal Atomization Device	AireHealth™ Nebulizer
K Number	K240114	K153470	K201167
Regulatory			
Indication for Use	The UltraEzAir® is a topical anesthesia applicator used to apply topical anesthetic to a patient's oropharynx and upper airway region through the working channel of a flexible nasal laryngoscope using air flow. The device is designed for and intended to be used by physicians trained and experienced in flexible endoscopic techniques for elective outpatient procedures such as: - Transnasal esophagoscopy - Fiberoptic endoscopic evaluation of swallowing with sensory testing (FEES/ST) - Vocal fold injections - Laryngeal biopsies - Laryngeal mass excisions - Laser excisions - Stroboscopy Dynamic voice assessment - Dynamic voice assessment - Peritonsillar abscess drainage	The MADgic LaryngoTracheal Mucosal Atomization Device is intended for the application of topical anesthetics to the oropharynx and upper airway region.	The AireHealth™ Nebulizer electronic vibrating mesh nebulizer is designed to nebulize liquid medications for inhalation by a patient. The AireHealth™ Nebulizer may be used in adults or children 5 years of age and older. The AireHealth™ Nebulizer is a portable Nebulizer for use in and out of the home environment. The AireHealth™ Nebulizer is not intended as a life sustaining or life supporting device. The AireHealth™ Nebulizer is not intended for use with Pentamidine.

Device	Subject Device	Predicate Device	Reference Device
	The safety and effectiveness of this device for use in the performance of topical anesthesia of the lower airways (below the level of the trachea) have not been established.		
Regulation Number	21 CFR 868.5170	21 CFR 868.5170	21 CFR 868.5630
Regulation Name	Laryngotracheal Topical Anesthesia Applicator	Laryngotracheal Topical Anesthesia Applicator	Nebulizer
Device Class	Class II	Class II	Class II
Product Code	CCT	CCT	CAF
Product Classification	Applicator (Laryngo-Tracheal), Topical Anesthesia	Applicator (Laryngo-Tracheal), Topical Anesthesia	Nebulizer (Direct Patient Interface)
Prescription Use	Yes	Yes	Yes
Intended Use			
Method of Operation	Application of topical anesthetic to a patient's oropharynx and upper airway region through the working channel of the flexible nasal laryngoscope using air flow	Application of topical anesthetics to the oropharynx and upper airway region	Nebulization of liquid medications for inhalation by a patient though the nasal or oral cavity
Environment of Use	Professional healthcare setting	Professional healthcare setting	In Home or Out of Home Use
Patient Population	Adult patients requiring topical anesthesia of oropharynx and upper airway region prior to endoscopic examination	Patients requiring topical anesthesia before intubation	Children 5 years of age or older and adults requiring nebulized liquid medication for inhalation
Intended Medications	4% topical lidocaine solution	Topical anesthetic solution (including 4% topical lidocaine)	Liquid medication for inhalation
Dosage Amount	User Controlled – Maximum of 0.4 ml (16 mg) of 4% topical lidocaine solution at High Mist Density setting during typical 5-minute delivery time	User Controlled – 2.8 ml lidocaine from a 3ml Syringe	Unknown

Device	Subject Device	Predicate Device	Reference Device
Device Features			
Typical Particle Size	70% of particles are greater than 11.72 microns and average particle size is 12 microns. Particle size range is 0.54 to > 14.9 microns.-	30-100 microns	2.0-6.0 microns
Piezoelectric Transducer Operating Frequency	1.66 MHz ± 50 kHz	N/A	115kHz
Method of Operation	**Previous Submission** Delivery form is a fine mist using piezoelectric technology and air flow through an endoscope. Device does not come into direct contact with patient.	Delivery form is a fine spray mist generated by piston syringe. Device comes into direct contact with patient	Inhalation by a patient. Nebulizes liquid medications using vibrating mesh nebulizer incorporated with a piezoelectric transducer.
Visualization of Target Anatomy	Flexible Nasal Laryngoscope	Laryngoscope	N/A
Rate of Anesthetic Delivery	Variable between 0.062 and 0.077 mL/min	Unknown	Minimum nebulization rate of 0.25 mL/min
Flow Rate	1.5 L/min	Unknown	Unknown
Hardware			
Sterilization	Non-sterile; Single use	Non-sterile; Single use	N/A
Shelf Life of Tubing	2 years from date of manufacture	Three (3) years from date of manufacture	N/A
Use Life of Unit	3 years or 2,500 5-minute uses whichever comes first	N/A	3 Years
Energy Source	External	Manual	Internal
Operating Temperature	15 to 30 °C	Unknown	5 to 38 °C
Operating Humidity	30 to 75% Relative Humidity	Unknown	15 to 90% Relative Humidity
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Per ISO 10993-1

1.7 Performance Testing Summary

Summary of Biocompatibility Testing:

The UltraEZAir is considered to be an externally communicating device with tissue contact for a limited duration (< 24 hrs) with indirect gas pathway contact. The biocompatibility evaluation for the UltraEZAir device was conducted in accordance with the guidance document "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation

and Testing Within a Risk Management Process,'" The testing included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

Per ISO 18562-1 "Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process", Gas Pathway Testing using the methods in ISO 18562-2 "Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter" and ISO 18562-3 "Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)" was completed as part of the biocompatibility testing.

Summary of Non-Clinical Functional and Performance Testing

Reprocessing instructions for the reusable Base were evaluated in the Human Factors testing.

Non-clinical bench performance testing was performed on the subject device including verification/validation testing to functional specifications, which demonstrated that the device is as safe and effective as the predicate device.

The following Functional and Performance Bench testing has been completed:

Testing to IEC 60601-1, IEC 60601-1-2
Testing to AIM 7351712 for RFID Interference
Device Characterization for: Flow Rate, Delivery Rate, Particle Size, Back Pressure, Pressure Over Time, Air Flow Rate Over Time, and Filter Efficiency
Human Factors Engineering per IEC 62366
Small Bore Connections Evaluation
System Verification: Inspection and Non-Functional System Labeling Inspection
Packaging/Shipping Validation

Together, these verification/validation activities successfully demonstrated that the device correctly performs as designed, has been validated for its intended use, and raises no new

questions regarding either safety or effectiveness when compared to the predicate device. Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the subject device.

Summary of Animal and Clinical Data

Animal and Clinical testing were not required for a determination of substantial equivalence of the UltraEzAir®.

1.8 Shelf Life

The useful life of the Base was determined to be 3 years after purchase or 2,500 5-minute uses, whichever comes first.

The shelf life of the non-sterile Mist Assembly and Delivery Lines were evaluated by AirKor® and it has been concluded that the Mist Assembly and Delivery Lines are not susceptible to degradation that would lead to functional failure. However, the shelf life of the Mist Assembly and Delivery Lines were determined to be two years from date of manufacture.

1.9 Conclusion

AirKor® considers the UltraEzAir® to be substantially equivalent to the The MADgic Laryngo-Tracheal Mucosal Atomization Device. The information presented in the 510(k) supports that the UltraEzAir® is as safe, as effective, and performs as well as the predicate devices and is substantially equivalent to the identified predicate and reference devices in design rationale, methodology of use, and performance.