August 13, 2025

Pipeline Medical Products, LLC
% Keira Jessop
Regulatory Affairs Consultant
AlvaMed, Inc.
935 Great Plain Avenue, Unit 166
Needham, Massachusetts 02492

Re: K243579
Trade/Device Name: Aero Jet Ventilation Catheter
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: November 19, 2024
Received: July 2, 2025

Dear Keira Jessop:

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243579

Device Name

Aero Jet Ventilation Catheter

Indications for Use *(Describe)*

The Aero Jet Ventilation Catheter is indicated to be used as a device for ventilating the patient by the administration of oxygen and air, a technique referred to as jet ventilation.

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
K243579

1.1 Name and Address of Submitter

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Pipeline Medical Products, LLC
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1.2 Correspondent/Primary Contact Person

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1.3 Submission Information

Date Summary Prepared: August 11, 2025

Subject Device:	Trade/Device Name:	Aero Jet Ventilation Catheter
	Manufacturer:	Pipeline Medical Products, LLC
	Regulation Number:	21 CFR 868.5730
	Regulation Name:	Tracheal Tube
	Regulation Class	II
	Product Code:	BTR
	Review Panel:	Anesthesiology
Primary Predicate Device:	Clearance:	K922880
	Trade/Device Name:	XOMED TREACE JET VENTILATION TUBE
	Manufacturer:	XOMED-TREACE, INC.
	Regulation Number:	21 CFR 868.5730
	Regulation Name:	Tracheal Tube
	Regulation Class:	II
	Product Code:	BTR
	Review Panel:	Anesthesiology

Valid Predicate Discussion

The XOMED TREACE JET VENTILATION TUBE was selected as the valid predicate device used to support the 510(k) submission because it was cleared using well-established methods. XOMED TREACE JET VENTILATION TUBE was the predicate device identified which meets the expected predicate performance and was most technically like the subject device. 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.

Table 1: Valid Predicate Device

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**
XOMED TREACE JET VENTILATION TUBE	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 Aero Jet Ventilation Catheter is a sterile, single-use, prescription medical device that consists of a three lumen PTFE extrusion, a PEBAX centering feature at the distal end, three (3) MABS female luer connectors, silicone extrusion to connect the connectors to the main shaft, and four (4) polyeolefin color coded marker bands for identification of connectors and depth marking. A removable stainless-steel stylet is included to support the device during insertion. It has a nominal insertion length of 23 cm and nominal OD of 3.85 mm. It is inserted orally and placed subglottic. It provides jet ventilation and allows for monitoring of pressure and $EtCO_2$.

1.5 Indications for Use

The Aero Jet Ventilation Catheter is indicated to be used as a device for ventilating the patient by the administration of oxygen and air, a technique referred to as jet ventilation.

1.6 Summary of Technological Characteristics

The following table provides an overview of general technological characteristics in comparison to the predicate 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.

	Subject Device	Predicate Device
Name	Aero Jet Ventilation Catheter	XOMED TREACE JET VENTILATION TUBE (Hunsaker Mon-Jet Ventilation Tube)
K#	K243579	K922880
Regulation	21 CFR 868.5730	21 CFR 868.5730
Product Code	BTR	BTR
Class	II	II
Indication for Use	The AeroJet Ventilation Catheter is indicated to be used as a device for ventilating the patient by the administration of oxygen and air, a technique referred to as jet ventilation.	The Hunsaker Mon-Jet Ventilation Tube is intended to be used as a device for the ventilating the patient by the administration of pressurized anesthesia gases, a technique referred to as jet ventilation, in microlaryngeal surgical procedures.
Use/Application/ Operating principles(s)	Delivers gases to patient's lungs via connection to a jet ventilator for intermittent jet ventilation delivery of oxygen and wall air; allows for monitoring of pressure and End-tidal CO_2	Delivers gases to patient's lungs via connection to a jet ventilator for intermittent jet ventilation delivery of oxygen and wall air; allows for monitoring of pressure and End-tidal CO_2.
Configuration	Connector Main Tube with Distal Centering Feature $PetCO_2$ Monitor Tube Luer Jet Tube Pressure Monitoring Tube Stylet	Connector Main Tube with Distal Centering Feature PetCO2 Monitor Tube Luer Jet Tube Pressure Monitoring Tube Stylet
Device Design	Consists of a three lumen PTFE extrusion, a PEBAX centering feature at the distal end, three (3) MABS female luer connectors, silicone extrusion to connect the connectors to the main shaft, and four (4) polyolefin color coded marker bands for identification of connectors and depth marking. A removable stainless-steel stylet is included to support the device during insertion.	Consists of a dual-lumen extrusion, a three-way stopcock to select between the patient respiratory gas and gas monitoring port lines and centering feature as the distal end. A stainless-steel wire is provided within the larger lumen. Both lumens are fitted at the proximal end with a female luer type fitting for connection to operating room gas suppliers and monitoring equipment.
Diameter	O.D.: 3.85 mm	O.D.: 4 x 3 mm (oval shaped)
Insertion Length	23 cm	23 cm

Intended Population	Adult	Adult
Anatomical Insertion Site	Oral	Oral
Anatomical Placement Location	Subglottic	Subglottic
Single Use	Yes	Yes
Patient Contact Material	Shaft: PTFE, Basket: PEBAX, Stylet: Stainless Steel	Shaft: PTFE, Stainless Steel Basket: PEBAX with Stainless steel, Stylet: Stainless Steel
Laser Resistance	Tube's main shaft is inherently resistant to fire or flame when impacted by laser energies at the tested laser settings per ISO 11990:2018.	Tube's main shaft is inherently resistant to fire or flame when impacted by laser energy intensities commonly used in clinical practice.
Duration of Use	≤6 hours	≤6 hours
Biocompatibility	Complies with ISO 10993 and 18562 requirements	Complies with ISO 10993 requirements
Sterilization	Ethylene Oxide	Ethylene Oxide

Discussion on Indication Differences

The differences between the subject and predicate indication are that the predicate device include a change from "…administration of pressurized anesthesia gases…" to "…administration of oxygen and air…" and the removal of "in microlaryngeal surgical producedures". This difference has no impact on the intended use as oxygen and air are a subset of possible anesthesia gases and Jet ventilation typically only uses air and oxygen. Jet ventilation is conducted during microlaryngeal surgical procedures. No new questions of safety and efficacy are created by this change.

Discussion on Technical Differences

The overall configuration and materials between the subject and predicate device are the same. Insertion site and placement location are also the same.

The main technical difference is the shaft design. The subject device has three internal lumens within the shaft while the predicate has two. The second and third lumen of the subject device are used to monitor gas and pressure separately, while the second lumen of the predicate device is used to monitor both, but a stopcock is used to toggle between monitoring of the two characteristics.

The subject device includes the addition of color-coded markers for identification and an insertion depth marker, which the predicate device does not have.

The predicate device includes a stainless-steel wire within the larger lumen, while the subject device does not include this wire.

The tip/basket configuration of the subject device's shaft extends though the proximal opening of the basket to the distal end of the basket and has a molded distal tip as opposed to the predicate device's shaft ending at the proximal end of the basket and the distal tip of the basket is cinched.

These differences do not affect the safety and effectiveness of the device.

1.7 Performance Testing Summary

Summary of Biocompatibility Testing:

The Aero Jet Ventilation Catheter is considered to be a surface device with mucosal membrane contact with a limited duration (< 24 hrs). The biocompatibility evaluation for the Aero Jet 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

Per ISO 18562-1 "Biocompatibility evaluation of breathing gas pathways in healthcare applications" the following was conducted:

- Particulate Matter
- Volatile Organic Compounds
- Toxicological Risk Assessment

Summary of Non-Clinical Functional and Performance Testing

The following non-clinical functional and performance testing was performed:

- Packaging Integrity Testing
- Tensile Testing
- Dimensional Testing
- Occlusion Testing
- Flow Testing
- Bend Radius Testing
- Laser Testing per ISO 11990-1
- Leakage and cracking for small bore connectors per ISO 80369-20

Summary of Animal and Clinical Data

No animal or clinical studies were conducted for this submission.

1.8 Conclusion

Based on the testing performed it is concluded that the Aero Jet Ventilation Catheter is substantially equivalent and demonstrate that the device is as safe, as effective, and performs as well as the predicate device, the XOMED TREACE JET VENTILATION TUBE.