June 12, 2026

Spiro Robotics
Jackie Dulken
Director of Engineering and Operations
22320 Foothill Blvd
Suite 250
Hayward, CA 94541, USA

Re: K253437
Trade/Device Name: Spiro-VISTA
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: May 15, 2026
Received: May 15, 2026

Dear Jackie Dulken:

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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253437

Device Name
Spiro-VISTA

Indications for Use *(Describe)*
The Spiro-VISTA system is intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly during non-difficult and difficult tracheal intubation procedures. The system is for use in a hospital environment in adults that have been clinically evaluated for ETT size 5.0 to 7.0 mm ID.

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.

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510(k) SUMMARY
Spiro-VISTA

510(k) Number:	K253437
Applicant Name:	Spiro Robotics 22320 Foothill Blvd Suite 250 Hayward, CA 94541, USA
Contact Person:	Jackie Dulken Director of Engineering and Operations Email: jdulken@spirorobotics.com
Date Prepared:	June 12, 2026
Proprietary Name of Device:	Spiro-VISTA
Classification Name:	Tracheal Tube
Classification Panel:	Anesthesiology
Regulation Number:	21 CFR 868.5730
Regulation Class:	Class II
Product Code:	BTR
Predicate Devices:	
Device Name:	Ambu® aScopeTM 2/Ambu® aScopeTM Monitor
Manufacturer:	Ambu USA
Application Number:	K110962
Reference Devices:	
Device Name:	Auris Robotic Endoscopy System
Manufacturer:	Johnson & Johnson
Application Number:	K152319

1. Intended Use / Indications for Use

The Spiro-VISTA system is intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly during non-difficult and difficult tracheal intubation procedures. The system is for use in a hospital environment in adults that have been clinically evaluated for ETT size 5.0 to 7.0 mm ID.

2. Device Description

The Spiro-VISTA (Video Intubation System for Total Access) is a servo-controlled tracheal intubation platform intended to be used by qualified clinicians to aid in the placement of ETT during tracheal intubation. The full system consists of an external

display and three handheld components: 1) Base; 2) channeled laryngoscope blade (Blade); and 3) flexible intubation scope (FIS).

The Base includes a stationary video baton with camera sensor (Video Laryngoscope [VL] camera) which provides panoramic views of the patient's upper airway anatomy, similar to conventional video laryngoscopes. The Base also includes drive mechanisms to maneuver the FIS (advance/retract and bending section deflection) and the electronics to operate the system.

The channeled laryngoscope blade is a single-use, sterile (EO), disposable component that connects to the Base and is inserted into the patient's airway to provide initial visualization of the upper airway anatomy and laryngeal structures. The Blade includes a joystick and buttons to maneuver the FIS, a window for the VL camera, and a channel that houses the endotracheal tube.

The flexible intubation scope is a single-use, sterile (EO), disposable component that connects to the Base giving the device a second camera sensor (FIS camera) for close-up views, dynamic views of both the upper and lower airway anatomy. The FIS features a distal bending section which is controlled manually by the operator via controls on the Blade.

Once the three handheld components are assembled, a standard ETT (not a component of the Spiro-VISTA system) slides over the flexible insertion cord of the FIS engaging with the ETT retainer on the FIS, and then is positioned in the channel of the Blade.

The handheld portion of the system connects to an external display via the video cable on the Base. The external display provides power to the Base and receives and transmits data to and from the Base, including live video feeds from both cameras.

The handheld portion of the system is inserted into the patient's upper airway to visualize the laryngeal structures. Using the Blade's joystick and buttons, the operator navigates the FIS to the patient's tracheal carina. The operator then advances the ETT out of the Blade channel and slides the ETT over the FIS into the patient's trachea under direct vision provided by both cameras. Once the endotracheal tube has been properly positioned, the operator stabilizes the ETT position while withdrawing the device from the patient's airway.

3. Summary of Technological Characteristics Compared to Predicate and Reference Devices

The intended use for Spiro-VISTA is the same as that of the Ambu® aScope. Both are intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly during non-difficult and difficult intubation procedures.

The Spiro-VISTA system combines the elements of a video laryngoscope (Class I 510(k) exempt [product code CCW] blade plus base with video baton) and a servo-controlled flexible intubation scope for tracheal intubation to assist clinicians with the placement of an endotracheal tube during tracheal intubations.

The subject and predicate devices utilize very similar flexible intubation scopes with maneuverable tips, flexible insertion cords, with CMOS cameras and LED lights located at the distal tip of the endoscope. In addition, both the subject and predicate devices use external monitors to display video feeds from the endoscopes to the screen by connecting a video out cable to an external displaying unit. The subject and predicate flexible intubation scopes are both single use and sterilized via ethylene oxide. While there are minor differences in the outer diameter of the flexible endoscope's shaft and tip, the inner diameter of the working channel, field of view, depth of field, and working length, non-clinical testing confirmed that these differences do not raise any new questions of safety or effectiveness.

With regard to the servo-controlled nature of the flexible scope, Spiro Robotics relies on comparison to the reference device, the Auris Robotic Endoscopy System (ARES) (K152319). The ARES is intended to be used to provide visualization to the bronchial tree during bronchoscopic procedures and consists of four major components, (1) the Patient Side System (PSS), (2) Controller Cart, (3) Surgeon Console (also known as the Master Device Workstation) and (4) the Bronchoscope and Accessories. The subject and reference devices utilize the same method of distal tip movement (pull wires) and rely on an electromechanical method (servo/stepper motors + software) for pulling wires. In addition, in both cases there are two axes of articulation, axial advancement is electromechanically controlled (motors +software), and the movement of the bronchoscope requires continuous direct control by the physician. There are minor differences, such as the location of the joystick and buttons (device body for the subject device as opposed to pendant controller for the reference device). These differences are ergonomic in nature and do not raise any new questions of safety or effectiveness.

The non-clinical testing conducted indicates that the Spiro-VISTA system meets its defined specifications, performs as intended and does not raise any new questions of safety or effectiveness.

Table 1 provides a comparison of the technological characteristics for the Spiro-VISTA and the predicate and reference devices.

Table 1
Comparison of Characteristics for the Subject, Predicate and Reference Devices

	Subject Device: Spiro-VISTA System	Predicate Device: Ambu® aScope	Reference Device: Auris Device	Comments
Device Name	Spiro-VISTA System	Ambu® aScope™ 2/Ambu® aScope™ Monitor	Auris Robotic Endoscopy System (ARES)	N/A
510(K) Number	TBD	K110962	K152319	N/A
Product Code	BTR	BTR	EOQ	Same
Regulation	868.5730	868.5730	874.4680	Same
Intended Use	The Spiro-VISTA system is intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly during non-difficult and difficult tracheal intubation procedures. The system is for use in a hospital environment in adults that have been clinically evaluated for ETT size 5.0 to 7.0 mm ID.	The Ambu® aScope ™ 2 is intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly or through an intubating laryngeal mask during non- difficult and difficult intubating procedures or for visualization of the airway during Percutaneous Tracheostomy (PT) procedures. The Ambu® aScope ™ 2 achieves its purpose by providing the user with a visual confirmation of where the tip of the Ambu® aScope™ 2 is in the human anatomy. The flexible tip of the Ambu®aScope 2 allows the user to guide the ETT in the desired direction. The system is for use in a hospital environment. The target population is adults/children that have been clinically evaluated for ETT size 6 or larger.	The Auris Robotic Endoscopy System (ARES) is intended to provide bronchoscope visualization of patient airways.	The subject and predicate devices have the same intended use; both are intended for aiding in the placement of an ETT directly during non-difficult and difficult tracheal intubation procedures in a hospital environment. The additional information provided in the statement for the predicate device provides additional details about its specific indications and the manner in which the predicate achieves its intended use. Similar additional information related to the subject device is found in the device description rather than the intended use statement.
Flexible Intubation Scope				
Tip	Maneuverable tip is controlled by the clinician.	Maneuverable tip is controlled by the clinician.		Same
Method of Distal tip movement	Pull wires	Pull wires		Same

	Subject Device: Spiro-VISTA System	Predicate Device: Ambu® aScope	Reference Device: Auris Device	Comments
Insertion Cord	Flexible	Flexible		Same
Camera/LED light source	CMOS camera. Camera and LED light located at distal tip	CMOS camera. Camera and LED light located at distal tip		Same
Field of View	120° +/- 4°	80°		Minor difference was evaluated in non-clinical testing, and FOV was found to be sufficient. Having a larger field of view allows the Spiro FIS to be closer to the anatomy while still allowing good visualization.
Depth of Field	3mm to ∞	9mm-18mm		Difference was evaluated in non-clinical testing, and DOF was found to be sufficient. Having a broader depth of field allows for better visualization without additional risks.
Sterility	EO	EO		Same
Single Patient Use	Single Use	Single Use		Same
Outside diameter of flexible shaft and tip	4.7mm	5.4mm		Minor difference was evaluated in non-clinical testing, and was found to be compatible with the range of ETT sizes indicated for use with the Spiro-VISTA. The smaller diameter allows for the subject device to be used with smaller ETTs than the predicate.
Inside Diameter of working channel	1.0 mm	0.8mm		Minor difference was evaluated in non-clinical testing, and was

	Subject Device: Spiro-VISTA System	Predicate Device: Ambu® aScope	Reference Device: Auris Device	Comments
				found to be sufficient for administering local anesthetics and clearing camera obstructions.
Working length	330mm	630mm		Subject device working length is shorter than the predicate device working length. However, 330 mm is sufficient to achieve visual confirmation that the ETT has been placed at the appropriate depth in the trachea.
External Display				
Display	Displays images from endoscope and video laryngoscope simultaneously on the screen by connecting Video Out Cable to external displaying unit.	Displays image from endoscope to screen by connecting Video Out Cable to external displaying unit.	Displays image from endoscope to screen by connecting Video Out Cable to tower (external displaying unit).	Subject device displays an additional video feed from the video laryngoscope, that neither the predicate or reference device display. Additional video feed from video laryngoscope does not raise new questions of safety or effectiveness.
System				
Form factor	Hand held Endoscope and Controller (Base) Display can be mounted on a Stationary Cart	Hand held Endoscope and Controls Display can be mounted on IV Pole or placed on solid surface		Subject device is similar to the predicate device, with the only difference being the way that the display can be mounted. Non-clinical testing showed that this difference does not raise new

	Subject Device: Spiro-VISTA System	Predicate Device: Ambu® aScope	Reference Device: Auris Device	Comments
				questions of safety or effectiveness.
Base				
Method of distal tip movement (pull wires)	Electromechanical (servo motors + software)		Electromechanical (servo/stepper motors + software)	Subject device is the same as the reference device.
Control/Physician interface	Joysticks and buttons located on the device body		Joysticks and buttons located on a pendant controller	Subject device is similar to the reference device. Both the subject and reference device use the same controls, however the location of the controls is different (device body vs pendant controller). These differences are ergonomic in nature and do not raise any new questions of safety or effectiveness.
Control of movement	Device requires continuous direct control by the physician user to maneuver the endoscope.		Device requires continuous direct control by the physician user to maneuver the endoscope.	Subject device is the same as the reference device.
Axis of articulation	2		2	Subject device is the same as the reference device.
Axial Advancement	Electromechanical (motors + software)		Electromechanical (motors + software)	Subject device is the same as the reference device.

4. Summary of Non-Clinical Performance Data

The company conducted extensive non-clinical testing which demonstrated that the Spiro-VISTA meets its design specifications and is substantially equivalent to the predicate and reference devices. Specifically, the following non-clinical testing was conducted:

- Sterilization Validation (TIR28, ISO 11607-1, ISO 11135, ISO 10993-7, and FDA Guidance Submission and Review of Sterility Information in Premarket Notification (510(k))
- Submissions for Devices Labeled as Sterile Package Integrity Testing (ASTM D4169)
- Shelf life Testing (ASTM F1980)
- Biocompatibility (FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", ISO 10993-5 (cytotoxicity), ISO 10993-10 (sensitization) and ISO 10993-23 (irritation))
- Software validation (FDA Guidance Content of Premarket Submissions for Device Software Functions, IEC 62304))
- Cybersecurity (FDA Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions)
- EMC Testing (IEC 60601-1-2)
- Electrical Safety Testing (FDA Guidance Electromagnetic Compatibility (EMC) of Medical Devices,IEC 60601-1, IEC 60601-2-18)
- Non-clinical Performance Testing
- Human Factors Validation (IEC 62366-1, FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices)

Testing demonstrated that the Spiro-VISTA met its performance specifications and performed as intended. All requirements were either fully met or determined to present no risk to patient safety or effective device use. In addition, the Spiro-VISTA was found to be substantially equivalent to the predicate and reference devices.

5. Substantial Equivalence Conclusion

After analyzing the intended use/indications for use, technological characteristics (including fundamental operating principle, functional characteristics, design features and performance characteristics) and labeling, the Company has concluded that the subject device, the Spiro-VISTA, is substantially equivalent to the predicate and reference devices. While there the subject device's technological characteristics differ slightly from the predicate/reference devices, these differences are ergonomic in nature and do not raise any new questions of safety or effectiveness. The non-clinical testing indicates that the Spiro-VISTA system meets its defined specifications, performs as intended and does not raise any new questions of safety or effectiveness.

Thus, the Spiro-VISTA is substantially equivalent to the predicate device, Ambu® aScopeTM 2/Ambu® aScopeTM Monitor, cleared in 2011 (K110962) and the reference device, Auris Robotic Endoscopy System (K152319).