July 10, 2026

Free Flow Medical, Inc.
Mark Mathis
CEO
44380 S Grimmer Blvd.
Fremont, California 94538-6385

Re: K254037
Trade/Device Name: LungFlow Airway Catheter
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: June 16, 2026
Received: June 17, 2026

Dear Mark Mathis:

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,

John S. Bender -S

for Ethan Nyberg, Ph.D.
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

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.	K254037

Please provide the device trade name(s).

LungFlow Airway Catheter

Please provide your Indications for Use below.

The LungFlow Airway Catheter has been designed to be used with bronchoscopes, endo-therapy accessories and ultrasound probe to guide the endo-therapy accessories or ultrasonic probe to the targeted area within the respiratory organs.

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)

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Information:	*807.92(a)(1), (2)*
Owner Name:	Free Flow Medical, Inc.
Address:	44380 S Grimmer Blvd Fremont, CA 94538-6385
Phone:	+1 (510) 255-0064
Contact Person:	Mark Mathis
Date Prepared:	30 June 2026

Device Information:	
Classification:	Class II
Trade Name:	LungFlow™ Airway Catheter
Common name:	Guide Sheath
Classification name:	Bronchoscope (Flexible or Rigid) and Accessories
Regulation number:	21 CFR 874.4680
Classification Code:	EOQ

Predicate Device *807.92(a)(3)*

The subject of this submission, the LungFlow Airway Catheter, is substantially equivalent to the predicate, Olympus Guide Sheath, XBO1-836-13, cleared by FDA through 510(k) K060243. The subject device has the same intended use and similar indications for use, design, material, operational principles, and performance as the predicate device, Olympus Guide Sheath, XBO1-836-13.

Device Description *807.92(a)(4)*

The Free Flow Medical LungFlow Airway Catheter is a sterile single use disposable bronchoscope accessory that is designed to be used with common therapeutic bronchoscopes with a 2.8mm instrument channel, and it provides a channel to deliver 2.0mm compatible bronchoscope accessories and ultrasonic probes for performing diagnostic and therapeutic procedures to airways beyond the reach of typical therapeutic bronchoscopes. The LungFlow Airway Catheter allows physicians to advance the endo-therapy accessories or guide an ultrasonic probe precisely to the target lesions repeatedly. The LungFlow Airway Catheter may be guided, during advancement, by a guidewire.

The LungFlow Airway Catheter is provided in a straight tip configuration and with tip shapes that vary in the amount of tip curvature in a single direction as well as an “S” curve so the catheter can be selected that best conforms to airway anatomy. The predicate device is provided

in a single straight tip shape. Both devices are configured with radiopaque markers to identify the distal tip when the procedure is assisted with x-ray.

The LungFlow Airway Catheter and the predicate device are sterilized using the same method, EO.

Intended Use / Indication for Use *807.92(a)(5)*
The LungFlow Airway Catheter has been designed to be used with bronchoscopes, endo-therapy accessories and ultrasound probe to guide the endo-therapy accessories or ultrasonic probe to the targeted area within the respiratory organs.

Substantial Equivalence
The LungFlow Airway Catheter has the same intended use and similar indications for use, design materials, technological characteristics, and performance characteristics as the predicate device. A comparison supporting substantial equivalence is provided in the table below.

Product	**LungFlow Airway Catheter**	**Olympus Guide Sheath, XBO1-836-13**	**Conclusion**
510(k) number	**Subject Device**	**K060243 – predicate**	
Manufacturer	**Free Flow Medical, Inc.**	**Aomori Olympus Co., Ltd.**	
Product Code	EOQ	EOQ	SAME
Regulation	21 CFR 874.4680	21 CFR 874.4680	SAME
Intended Use / Indication	The LungFlow Airway Catheter has been designed to be used with bronchoscopes, endo-therapy accessories and ultrasound probe to guide the endo-therapy accessories or ultrasonic probe to the targeted area within the respiratory organs.	This instrument has been designed to be used with Olympus bronchoscopes, endo-therapy accessories and ultrasound probe to guide the endo-therapy accessories or ultrasonic probe to the targeted area within the respiratory organs.	Substantially Equivalent
Materials			
Hub, Female Luer	Polycarbonate	Unknown Polymer	Substantially Equivalent
Trunk Liner	PTFE	Unknown Polymer	Substantially Equivalent
Braid (Trunk Reinforcement)	304 Stainless Steel	None	Substantially Equivalent
Trunk Outer jacket	63D Pebax	Unknown Polymer	Substantially Equivalent

Product	**LungFlow Airway Catheter**	**Olympus Guide Sheath, XBO1-836-13**	**Conclusion**
510(k) number	**Subject Device**	**K060243 – predicate**	
Manufacturer	**Free Flow Medical, Inc.**	**Aomori Olympus Co., Ltd.**	
Radiopaque Marker	90% Platinum / 10% Iridium	Unknown Metal	Substantially Equivalent
Design & Technological Characteristics			
Tip Shape	Straight, 45 Degree, J, U and S curves	Straight	Substantially Equivalent
Outer Diameter	2.4mm	2.7mm	Substantially Equivalent
Inner Diameter	2.0mm	2.1mm	Substantially Equivalent
Sheath Working Length	900mm	900mm	Substantially Equivalent
Required Channel Size (Minimum Diameter)	2.8mm	2.8mm	Substantially Equivalent
Fluoro Tip for X-Ray Monitoring	Provided by Radiopaque Marker	Provided by Radiopaque Marker	Substantially Equivalent
Performance Testing			
Fits through $\geq$ 2.8mm bronchoscope	Yes	Yes	Substantially Equivalent
Number of Times Deliverable through bronchoscope without damage	15	15	Substantially Equivalent
Meets Biocompatibility according to ISO 10993	Yes	Yes	Substantially Equivalent

Technological Characteristics *807.92(a)(6)*

The technological differences between the subject and predicate devices are limited to dimensional and design features (tip shape, inner and outer diameters, and working-channel compatibility). These differences do not change the intended use, fundamental scientific technology, or operating principles to guide the endo-therapy accessories or ultrasonic probe to the targeted area within the respiratory organs via a bronchoscope.

Summary of Non-Clinical Test - Performance and Safety Testing *807.92(b)(1)*

LungFlow Airway Catheter was evaluated and underwent appropriate non-clinical performance and safety testing in accordance with applicable external standards and internal procedures,

including biocompatibility, sterilization, shelf-life, and bench testing, to support a determination of substantial equivalence to the predicate device.

Biocompatibility
The LungFlow Airway Catheter was classified as an externally communicating device with tissue and limited contact duration (<24 hours). In accordance with ISO 10993-1 and FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"" The following tests were performed.

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Intracutaneous (Intradermal) Reactivity Test (ISO 10993-10)

All tests passed the acceptance criteria, and the test reports were determined to support the biocompatibility of the device for its intended use.

Sterilization and Shelf-life
The LungFlow Airway Catheter is sterilized using Ethylene Oxide (EO) to ensure a SAL of 10^{-6} according to international sterilization standard ISO 11135:2014.

Shelf-life: LungFlow Airway Catheter met 36 months shelf-life study requirements including package performance testing according to packaging standards ASTM F1886, ASTM F2096, and ASTM F88. In addition, functional testing was performed on the LungFlow Airway Catheter to ensure that device performance is not affected by aging. All tests met the acceptance criteria. The test results support the LungFlow Airway Catheter and sterile barrier system shelf life of 36 months.

Performance Testing
The performance of each LungFlow Airway Catheters and the Olympus Guide Sheath, XBO1-836-13 was tested in worst case conditions which included passing devices through bronchoscopes that are fixed in a tortuous path in 37 degree C water. Each device was tested repeatedly in the tortuous path delivering and recapturing the device a minimum of 15 cycles without damage. LungFlow Airway Catheters and the predicate fit through a 2.8mm channel bronchoscope without interference. To confirm joint strength integrity, a joint pull test demonstrated that the joints of the of the LungFlow Airway Catheters and the predicate exceeded 5 lbs.

Summary of Clinical Tests *807.92(b)(2)*
Not applicable. Based on the substantial equivalence discussion and the testing results from bench tests, it was determined that a clinical study was not required to demonstrate substantial equivalence with the predicate device.

Conclusion *807.92(b)(3)*
In summary, the LungFlow Airway Catheter is substantially equivalent to the predicate, Olympus Guide Sheath, XBO1-836-13 (K060243) have the same intended use and similar indications for use design, material, operational principles, and performance. The technological

differences between the subject and predicate devices are limited to minor dimensional and design variations (e.g., tip shape, inner and outer diameter, and working-channel compatibility) and do not alter the intended use, fundamental scientific technology, or the operating principles to guide the endo-therapy accessories or ultrasonic probe to the targeted area within the respiratory organs via a bronchoscope. Safety testing (including ethylene oxide sterilization and biocompatibility) and performance testing (including dimensional verification, mechanical strength, tortuosity-model performance, and bronchoscope compatibility) demonstrate that the subject device performs as intended and is comparable to the predicate. Collectively, the performance and safety data provided in this 510(k) are sufficient to support a determination that the LungFlow Airway Catheter is substantially equivalent to the predicate device.