March 12, 2026

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

Re: K254040
Trade/Device Name: LungFlow Basket Catheter
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: KTI
Dated: December 15, 2025
Received: December 16, 2025

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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.

Submission Number *(if known)*

K254040

Device Name

LungFlow Basket Catheter

Indications for Use *(Describe)*

The LungFlow Basket Catheter is intended to be used to endoscopically remove foreign bodies from the airway.

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

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:	12, February 2026

Device Information:	
Classification:	Class II
Trade Name:	LungFlow™ Basket Catheter
Common name:	Basket Graspers
Classification name:	Bronchoscope Accessory
Regulation number:	21 CFR 874.4680
Classification Code:	KTI

Predicate Device *807.92(a)(3)*
The subject of this submission, the LungFlow Basket Catheter, is substantially equivalent to the predicate, Boston Scientific Corporation Microvasive® Zero Tip™ Airway Retrieval Basket cleared by FDA through 510(k) K020765. The subject device has the same intended use, indications for use, design, material, operational principles, and performance as the predicate device, Microvasive® Zero Tip™ Airway Retrieval Basket.

Device Description *807.92(a)(4)*
The Free Flow Medical LungFlow Basket Catheter is a sterile, single use disposable foreign body retrieval device. The basket is designed to fully expand to make 360-degree contact with the airway wall to enable removal of foreign bodies which include inhaled objects or material, incidental medical debris, mucus, necrotic or potentially infective tissue or excised tissue from the airway, as the device is retracted proximally.

The LungFlow Basket Catheter consists of a flexible coiled stainless steel wire trunk with a multi-wire 360-degree super-elastic nitinol basket at the distal end. The LungFlow Basket Catheter is designed to be delivered through the working channel (2.0mm and 2.8mm or larger) of an endoscope, such as a rigid or flexible bronchoscope.

The LungFlow Basket Catheter is provided in configurations with a handle to manually assist the distal basket expansion or with a self-expanding distal basket.

The LungFlow Basket Catheter may be delivered into distal lung airways using a compatible airway catheter if the catheter has been advanced through a therapeutic bronchoscope and into lung tissue with guidance provided by bronchoscope. Both manual expansion and self-expanding configurations are intended to be delivered distal to a foreign body before expansion. The LungFlow Basket Catheter will be provided in configurations that can expand up to 30mm in diameter. The basket is designed to fully expand to make 360-degree contact with the airway wall to enable reliable removal of foreign bodies from the airway.

Each LungFlow Basket Catheter is individually packaged and sterilized using electron beam (e-beam) radiation.

The LungFlow Basket Catheter is manufactured in the United States.

Intended Use / Indication for Use *807.92(a)(5)*
The LungFlow Basket Catheter is intended to be used to endoscopically remove foreign bodies from the airway.

Substantial Equivalence
Substantial equivalence with regard to the intended use/indications for use, materials, design and technological characteristics, and performance of the LungFlow Basket Catheter and the predicate device is outlined in the table below

Product	**LungFlow Basket Catheter**	**Microvasive Zero Tip Airway Retrieval Basket**	
510(k) number	**Subject Device**	**K020765 – predicate**	**Conclusion**
Manufacturer	Free Flow Medical, Inc.	Boston Scientific Corporation	
Product Code	KTI	KTI	SAME
Regulation	21 CFR 874.4680	21 CFR 874.4680	SAME
Intended Use / Indication			
Intended Use / Indications for Use	The LungFlow Basket Catheter is intended to be used to endoscopically remove foreign bodies from the airway.	The Microvasive® Zero Tip™ Airway Retrieval Basket is intended to be used to endoscopically remove foreign bodies from the airway.	SAME
Materials			
Basket	Nitinol (ASTM F2063-18)	Nitinol	SAME
Trunk	Stainless Steel (Type 304)	Stainless Steel (Type is unknown)	SAME
Pull Wire	Stainless Steel (Type 304)	Stainless Steel (Type is unknown)	SAME

Product	**LungFlow Basket Catheter**	**Microvasive Zero Tip Airway Retrieval Basket**	
510(k) number	**Subject Device**	**K020765 – predicate**	**Conclusion**
Handle	ABS Polymer	Polymer (Type is unknown)	Substantially Equivalent
Design & Technological Characteristics			
Tip design	No Tip	Zero Tip X	Substantially Equivalent
Basket Style	Polyhedron	Rectangular	Substantially Equivalent
Basket Size (OD) When Fully Opened	10, 16, 30mm	12, 16mm	Substantially Equivalent
Number of Basket Wires	32 wires or 64 wires	4 wires	Substantially Equivalent
Sheath Working Length	120cm	120cm	SAME
Sheath OD	1.8mm	0.8mm	Substantially Equivalent
Minimum Bronchoscope Working Channel	2.0mm or 2.8mm	2.0mm	Substantially Equivalent
Handle	Optional	Detachable	Substantially Equivalent
Introducer	No	Yes	Substantially Equivalent
Performance Testing			
Fits through $\geq$ 2.0mm bronchoscope	Yes	Yes	SAME
Basket opens fully	Yes	Yes	SAME
Number of Times Deliverable through bronchoscope without damage	15	15	SAME
Meets Biocompatibility according to ISO 10993	Yes	Yes	SAME

Technological Characteristics *807.92(a)(6)*

The technological differences between the subject and predicate devices are limited to dimensional and design features (tip geometry, basket configuration, wire count, and working channel compatibility). These differences do not change the intended use, fundamental scientific technology, or operating principle of mechanical basket foreign body capture and retrieval via a bronchoscope. Bench testing (dimensional verification, mechanical strength, performance in

tortuosity models, and bronchoscope compatibility) demonstrate that the subject device performs as intended compared to the predicate.

Summary of Non-Clinical Test - Performance and Safety Testing *807.92(b)(1)*
LungFlow Basket 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 Basket 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
Sterilization validation is performed using electron beam radiation to ensure a SAL of 10^{-6} according to international sterilization standards ISO 11137-1 and ISO 11137-2.

Shelf-life: LungFlow Basket Catheter met 6 months (accelerated) aging study requirements including package performance testing according to packaging standards ASTM D4169, ASTM F1980, ASTM F1886, ASTM F2096, ASTM F88, and ISO11607-1. In addition, functional testing was performed on the LungFlow Basket Catheter to ensure that device performance is not affected by aging. All tests met the acceptance criteria. The LungFlow Basket Catheter sterile barrier system maintains sterility integrity over 6 months accelerated aging.

Performance Testing
The performance of each LungFlow Basket Catheters and the Boston Scientific Corporation Microvasive® Zero Tip™ Airway Retrieval Basket 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 Basket Catheters and the predicate fit through a 2.0mm or larger channel bronchoscopes without interference. A joint pull test of LungFlow Basket 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 Basket Catheter and the Boston Scientific Corporation Microvasive® Zero Tip™ Airway Retrieval Basket (K020765) have the same indications for use and similar technological characteristics. The technological differences between the subject and predicate devices are limited to minor dimensional and design variations (e.g., tip geometry, basket configuration, wire count, and working-channel compatibility) and do not alter the intended use, fundamental scientific technology, or the operating principle of mechanical foreign-body capture and retrieval via a bronchoscope. Safety testing (including e-beam 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 Basket Catheter is substantially equivalent to the predicate device.