



September 23, 2026

Hunan Vathin Medical Instrument Co., Ltd.
Fei Lina
General Manager
1/F, Bldg. 12, Innovation And Entrepreneurship Service Center
No 9 Chuanqi W. Rd., Jiuhua Economic Development Zone
Xiangtan, Hunan 411100
China

Re: K261637

Trade/Device Name: Single-use Flexible Bronchoscope
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: August 24, 2026
Received: August 24, 2026

Dear Fei Lina:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

JOYCE C.

LIN-S



for Shu-Chen Peng, Ph.D.

Assistant Director

DHT1B: Division of Dental and

ENT 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.

K261637

?

Please provide the device trade name(s).

?

Single-use Flexible Bronchoscope

Please provide your Indications for Use below.

?

The Single-use Flexible Bronchoscope is designed for use with Vathin Display Units. It is used for airway and bronchus examination, diagnosis and treatment.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☐ Adults (22 years old and greater)

?

510(k) summary

I Submitter

Device submitter: Hunan Vathin Medical Instrument Co., Ltd.
Address: 1/F, Building 12, Innovation and Entrepreneurship Service Center, No 9 Chuanqi west road, Jiuhua Economic Development Zone, 411100 Xiangtan, Hunan, China
Contact person: Fei lina
Title: General Manager
Phone: +86-18017856052
E-mail: lily@zothin.com

II Device

Trade Name of Single-use flexible Bronchoscope
Device:
Model: BC-P1600、BC-P1601、BC-P1602、BC-P1603、BC-P1604、BC-P1700、BC-P1600-L、BC-P1601-L、BC-P1602-L、BC-P1603-L、BC-P1604-L、BC-P1700-L、BC-P16001、BC-P16011、BC-P16021、BC-P16031、BC-P16041、BC-P17001、BC-P16001-L、BC-P16011-L、BC-P16021-L、BC-P16031-L、BC-P16041-L、BC-P17001-L
Regulation number: 21 CFR 874.4680
Regulation name: Bronchoscope (flexible or rigid) and accessories
Regulation Class: II
Product Code: EOQ
Review Panel: Ear Nose & Throat

III Predicate Device

Trade name: BFlex™ 2 Slim 3.8 Single-Use Bronchoscope
Regulation number: 21 CFR 874.4680
Regulation name: Bronchoscope (flexible or rigid) and accessories
Regulatory class: Class II
Product code: EOQ
Submitter: Verathon Medical

510(k) K230948
number:

IV Device description

The Single-use Flexible Bronchoscope is designed for use with Vathin Display Units. It is used for airway and bronchus examination, diagnosis and treatment.

There are 24 subject Bronchoscope models: BC-P1600、BC-P1601、BC-P1602、BC-P1603、BC-P1604、BC-P1700、BC-P1600-L、BC-P1601-L、BC-P1602-L、BC-P1603-L、BC-P1604-L、BC-P1700-L、BC-P16001、BC-P16011、BC-P16021、BC-P16031、BC-P16041、BC-P17001、BC-P16001-L、BC-P16011-L、BC-P16021-L、BC-P16031-L、BC-P16041-L、BC-P17001-L. The main differences between product models are in the length、pins of connector、Minimum Working Channel、Maximum Outer Diameter、Outer Diameter of Main Hose and whether they are self-locking.

V Indications for use

The Single-use Flexible Bronchoscope is designed for use with Vathin Display Units. It is used for airway and bronchus examination, diagnosis and treatment.

Intended Patient Population

All series of the Single-use Flexible Bronchoscope are intended for use in pediatric patients (6 years).

Those with a working length of 600mm or longer are also intended for use in adults .

Models	Intended Patient Population
BC-P1603、BC-P1604、BC-P1603-L、BC-P1604-L、BC-P16031、BC-P16041、BC-P16031-L、BC-P16041-L	6 – 18 years
BC-P1600、BC-P1601、BC-P1602、BC-P1600-L、BC-P1601-L、BC-P1602-L、BC-P16001、BC-P16011、BC-P16021、BC-P16001-L、BC-P16011-L、BC-P16021-L、BC-P1700、BC-P1700-L、BC-P17001、BC-P17001-L	6 years of age through adulthood

VI Comparison of technological characteristics with the predicate device

The Single-use Flexible Bronchoscope has the same intended use and principal

operation, the technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate device. Any differences in various attributes as listed below between the Single-use Flexible Bronchoscope and predicate device do not alter suitability of the proposed device for its intended use nor impact substantial equivalence with the predicate.

Device feature	Proposed Device	Predicate Device
Trade Name	Single-use Flexible Bronchoscope	BFlex™ 2 Slim 3.8 Single-Use Bronchoscope
Classification Name	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (Flexible Or Rigid)
Product Code	EOQ	EOQ
Regulation Number	21 CFR 874.4680	21 CFR 874.4680
Intended use	The Single-use Flexible Bronchoscope is designed for use with Vathin Display Units. It is used for airway and bronchus examination, diagnosis and treatment.	The BFlex™ 2 Slim 3.8 Single-Use Bronchoscope is intended to work with a video monitor, in conjunction with non-powered endoscopic accessories and other ancillary equipment, for endoscopy within the airways and tracheobronchial tree.
Application field	The device is for use in a hospital or qualified medical institution.	The BFlex™ 2 Single-Use system is for use in a hospital environment.
Patient population	All series of the Single-use Flexible Bronchoscope are intended for use in pediatric patients (6 years). Those with a working length of 600mm or longer are also intended for use in adult.	BFlex 2 Slim 3.8 indicate for patients ≥ 6 years and adults.
Scope type	Flexible	Flexible
Field of view (degree)	$120^{\circ} \pm 15\%$	120°
Direction of view(degree)	$0^{\circ} \pm 10^{\circ}$	0°



Device feature	Proposed Device	Predicate Device
Trade Name	Single-use Flexible Bronchoscope	BFlex™ 2 Slim 3.8 Single-Use Bronchoscope
Depth of view	3-100mm	5-50mm
Bending angle (degree)	Up: 210° Down: 210°	Up: 180° Down: 185°
Maximum insertion portion width(mm)	BC-P1600, BC-P1600-L, BC-P16001, BC-P16001-L, BC-P1601, BC-P1601-L, BC-P16011, BC-P16011-L, BC-P1602, BC-P1602-L, BC-P16021, BC-P16021-L, BC-P1603, BC-P1603-L, BC-P16031, BC-P16031-L, BC-P1604, BC-P1604-L, BC-P16041, BC-P16041-L: 2.8mm BC-P1700, BC-P1700-L, BC-P17001, BC-P17001-L: 3.3mm	3.8mm
Minimum insertion channel width(mm)	BC-P1600, BC-P1600-L, BC-P16001, BC-P16001-L, BC-P1601, BC-P1601-L, BC-P16011, BC-P16011-L, BC-P1602, BC-P1602-L, BC-P16021, BC-P16021-L, BC-P1603, BC-P1603-L, BC-P16031, BC-P16031-L, BC-P1604, BC-P1604-L, BC-P16041, BC-P16041-L: 1.2mm BC-P1700, BC-P1700-L, BC-P17001, BC-P17001-L: 1.7mm	1.2mm
Working length (mm)	BC-P1600, BC-P1600-L, BC-P16001, BC-P16001-L: 680mm BC-P1601, BC-P1601-L, BC-P16011, BC-P16011-L: 650mm BC-P1602, BC-P1602-L, BC-P16021, BC-P16021-L, BC-P1700, BC-P1700-L, BC-P17001, BC-P17001-L: 600mm BC-P1603, BC-P1603-L, BC-P16031, BC-P16031-L: 550mm BC-P1604, BC-P1604-L, BC-P16041, BC-P16041-L: 500mm	566mm

Device feature	Proposed Device	Predicate Device
Trade Name	Single-use Flexible Bronchoscope	BFlex™ 2 Slim 3.8 Single-Use Bronchoscope
Illumination source	LED	LED
Single-use	Yes	Yes
Biocompatibility	Cytotoxicity testing passed	Cytotoxicity testing passed
	Irritation testing passed	Irritation testing passed
	Sensitization testing passed	Sensitization testing passed
Sterilization	EO	EO

VII Summary of Non-clinical tests:

Biocompatibility testing

Biocompatibility of the Single-Use Flexible Bronchoscope was evaluated in accordance with ISO 10993-1:2025 for the body contact category of “Surface – Mucosal Membrane” with a contact duration of “Limited (< 24 hours)”. The following tests were performed, as recommended: Cytotoxicity, Irritation, Sensitization, Pyrogenicity and Acute systemic toxicity. All evaluation acceptance criteria were met.

Sterilization and shelf-life testing

Sterilization process of Single-use Flexible Bronchoscope has been validated according to ISO 11135, which thereby routine control and monitoring parameters of the process has been determined. Shelf-life and package of single-use flexible bronchoscope was validated.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Single-Use Flexible Bronchoscope. The system complies with the IEC 60601-1 and IEC 60601-2-18 for safety, the IEC 60601-1-2 for EMC and IEC 60601-4-2 for Electromagnetic immunity.

Performance testing

Bench testing was performed to ensure that the device met its design specifications and is substantially equivalent to the predicate device. The following performance testing was conducted.

- Optical tests: illuminance, Image brightness Uniformity , field of view, direction of view, geometric distortion, Depth of view, geometric distortion, resolution,

color rendering index, Related color temperature, color restoration, signal-to-noise ratio, dynamic range .

- Mechanical tests: working length, minimum instrument channel width, Insertion tube outer diameter, Maximum insertion outer diameter, bending angle, water delivery and attractive volume.
- Dimensional: Compared with the predicate device, the subject device features a slimmer insertion section and multiple available working length specifications. It can adapt to various clinical scenarios and meet diversified diagnosis and treatment needs. We have completed a full set of bench performance tests to evaluate structural strength, flexibility, maneuverability and functional performance. All tests met the predefined acceptance criteria, verifying that such dimensional modifications will not adversely affect the safety and effectiveness of the device. In summary, this dimensional difference is acceptable, and the subject device remains substantially equivalent to the predicate device.

Compatible display units

Trade Name	Model	510(k) number:
Digital video monitor	DVM-B1、 DVM-B2	K230536
Digital video monitor	DVM-D1、 DVM-D2	K242416

VIII Conclusion

Based on device comparison information and performance data, the differences in technological characteristics between the subject device and predicate device do not raise any different questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.