July 25, 2025

Hunan Vathin Medical Instrument Co., Ltd.
Jing Du
Representative Management
1/F, Building12, Innovation and Entrepreneurship Service Cen
ter, No. 9 Chuanqi West Road, Jiuhua Economic Development Zo
Xiang Tan, Hunan 411100
China

Re: K250232
Trade/Device Name: Vathin® Video Bronchoscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: June 25, 2025
Received: June 25, 2025

Dear Jing Du:

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,

Shuchen Peng -S

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
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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)*

K250232

Device Name

Vathin® Video Bronchoscope System

Indications for Use *(Describe)*

The Vathin®H-SteriScopeTM single-use flexible video bronchoscope has been designed to be used with the Vathin display unit, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree in patients.
The Vathin® Video Bronchoscope System is for use in a hospital environment.
The Vathin®H-SteriScopeTM single-use flexible video bronchoscope is a single-use device designed for use in adults, with the BCV1-02 and BCV1-C2 also designed for pediatric use (BCV1-02: 6 months to 6 years; BCV1-C2: 6 years and older).

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.

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92 on December 25th, 2024

1. Administrative information

Date of Summary prepared:	July 25th, 2025
Manufacturer information:	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: Ms. Fei Lina Phone: +86-18017856052 Fax: +86-731 5555 8558 E-mail: lily@zothin.com

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Vathin® Video Bronchoscope System
Classification name:	Bronchoscope (flexible or rigid) and accessories
Review Panel:	Ear Nose & Throat
Product Code:	EOQ
Device Class:	II
Regulation Number:	874.4680

3. Predicate Device Information

510k number	Sponsor	Device name/Model
K223836	Hunan Vathin Medical Instrument Co., Ltd.	Vathin® Video Bronchoscope System
K211947	Verathon Medical (Canada) ULC	GlideScope BFlex 2.8 Single-Use Bronchoscope
K230948	Verathon Medical (Canada) ULC	BFlex™ 2 Slim 3.8 Single-Use Bronchoscope

4. Device Descriptions

The Vathin® Video Bronchoscope System consists of Vathin®H-SteriScope™ Single use flexible Video Bronchoscope (model: BCV1-02, BCV1-C2) to be introduced within the airways or tracheobronchial tree and Vathin®VisionCenter™ Digital Video Monitor (model: DVM-B1, DVM-B2) for clinical image processing. The Vathin®H-SteriScope™ Single-use flexible bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. The

Vathin®VisionCentere™ Digital Video Monitor provides power and processes the images for medical electronic endoscope.
Vathin®H-SteriScope™ Single-use flexible Video Bronchoscope is a sterile single-use flexible bronchoscope. Vathin®H-SteriScope™ Digital Video Monitor is a reusable monitor.

5. Intended Use/Indications for Use

The Vathin®H-SteriScope™ single-use flexible video bronchoscope has been designed to be used with the Vathin display unit, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree in patients.
The Vathin® Video Bronchoscope System is for use in a hospital environment.
The Vathin®H-SteriScope™ single-use flexible video bronchoscope is a single-use device designed for use in adults, with the BCV1-02 and BCV1-C2 also designed for pediatric use (BCV1-02: 6 months to 6 years; BCV1-C2: 6 years).

6. Comparisons of technological characteristics with the predicate device

Single-use flexible Video Bronchoscope of BCV1-02, BCV1-C2, and Digital Video Monitor of DVM-B1, DVM-B2 are the legally market devices to which the subject device in this 510k submission claims substantial equivalence, and BFlex 2.8 & BFlex 2 Slim 3.8 bronchoscopes are referred as secondary predicated devices to extend the applicable patients. The subject and predicate devices have the same intended use, similar Indications for Use, same operating principle and same technological characteristics. See the following table for comparison information in details.

Item	Subject device (Vathin® Video Bronchoscope System, Pending)	Primary predicate device (Vathin® Video Bronchoscope System, K223836)	Secondary predicate device 1 (GlideScope BFlex, 2.8, K211947)	Secondary predicate device 2 (BFlex™ 2 Slim 3.8, K230948)	Comparisons
Model	Vathin®H-SteriScope™ Single-use flexible Video Bronchoscope: BCV1-02, BCV1-C2 Vathin® Digital Video Monitor: DVM-B1, DVM-B2	Vathin®H-SteriScope™ Single-use flexible Video Bronchoscope: BCV1-01, BCV1-02, BCV1-C1, BCV1-C2, BCV1-H1, BCV1-H2, BCV1-K1, BCV1-K2, BCV1-M1, BCV1-M2, BCV1-O1, BCV1-O2, BCV1-S1, BCV1- S2, BCV1-U1, BCV1-U2, BCV1-W1, BCV1-W2; Vathin® Displaying Unit: Vathin® Digital Video Processor: DVP-A1 Vathin® Digital Video Monitor: DVM-A1, DVM-A2 Vathin® Digital Video Monitor: DVM-B1, DVM-B2	BFlex™ 2 Ultraslim 2.8 GlideScope video monitor (GVM or Core monitors)	BFlex™ 2 Slim 3.8 GlideScope video monitor (GVM or Core monitors)	Identical, the models are included in the primary predicate device
Classification Name	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories	Identical
Product Code	EOQ	EOQ	EOQ	EOQ	Identical
Regulation number	874.4680	874.4680	874.4680	874.4680	Identical

Intended Use	The Vathin®H-SteriScope™ single-use flexible video bronchoscope has been designed to be used with the Vathin display unit, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree in patients. The Vathin® Video Bronchoscope System is for use in a hospital environment.	The Vathin®H-SteriScope™ Single-use flexible video bronchoscope has been designed to be used with the Vathin® display unit, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The Vathin® Video Bronchoscope System is for use in a hospital environment.	GlideScope® BFlex™ Single-Use Bronchoscopes are 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.	BFlex™ 2 Slim 3.8 Single-Use Bronchoscope is intended to work with the video monitor, in conjunction with non-powered endoscopic accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.	Identical
Population	Adults; BCV1-02: 6 months to 6 years; BCV1-C2: 6 years and older	Adults	6 months to 6 years	6 years	Substantial equivalence
Outside diameter of insertion shaft and distal tip	BCV1-02: 2.2mm BCV1-C2: 3.2mm	2.2/3.2/4.1/4.7/4.9/5.2/5.8/6.0/6.2 (mm)	2.8mm	3.8mm	Identical to Primary predicate device
Field of view	110° (horizontal/vertical)	110° (horizontal/vertical)	85° (horizontal/vertical)	85° (horizontal/vertical)	Identical to Primary predicate device
Direction of view (degree)	0°	0°	0°	0°	Identical
Depth of field	3-100mm	3-100mm	5-50mm	5-50mm	Identical to Primary predicate device

Minimum insertion channel width	BCV1-02: 0, not applicable BCV1-C2: 1.2mm	0/1.2/1.7/2.0/2.2/2.4/2.8/3.0/3.2 (mm)	0, not applicable	1.2mm	Identical
Working length	600mm/700mm	600mm/700mm	Not publicly available	Not publicly available	Identical to Primary predicate device
Digital video technology	CMOS	CMOS	Not publicly available	Not publicly available	Identical to Primary predicate device
Illumination source	LED	LED	LED	LED	Identical
Image/Video capture	Yes	Yes	Yes	Yes	Identical
Output formats	DVP-A1: DVI/USB DVM-A1 &DVM-A2: USB/HDMI DVM-B1 &DVM-B2: USB/HDMI	DVP-A1: DVI/USB DVM-A1 &DVM-A2: USB/HDMI DVM-B1 &DVM-B2: USB/HDMI	Not publicly available	Not publicly available	Identical to Primary predicate device
Single-use Bronchoscope	Yes	Yes	Yes	Yes	Identical
Biocompatibility	Conform to ISO 10993-1 series	Conform to ISO 10993-1 series	Conform to ISO 10993-1 series	Conform to ISO 10993-1 series	Identical
Sterility	Sterilized by Ethylene Oxide (EO)	Sterilized by Ethylene Oxide (EO)	Sterilized by Ethylene Oxide (EO)	Sterilized by Ethylene Oxide (EO)	Identical

The insertion pressure of the scope shaft tip is no greater for subject device than for the secondary predicate device (BFlex™ 2 Ultraslim 2.8 with the same pediatric indication) according to the results of comparison tests, despite the smaller outer diameter of subject device than the secondary predicate, to support the use of subject device in the pediatric airway.

The subject device and the predicate devices are similar/same in indication for use, operating principle, and technology characteristics. There is no significant difference between subject device and predicate devices, only minor differences existing will not raise any new issues on safety and effectiveness of the subject device.

7. Performance data

The following performance data were used or referred in support of the substantial equivalence determination.

7.1 Electrical Safety, Essential Performance and EMC

- ✧ IEC 60601-1: 2005+A1:2012+ A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ✧ IEC 60601-1-2: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ✧ IEC60601-2-18: 2009 Medical electrical equipment - Part 18: Particular requirements for the basic safety and essential performance of endoscopic equipment

7.2 Biocompatibility evaluation

- ✧ ISO 10993-1: 2018 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process
- ✧ ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity
- ✧ ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ✧ ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ✧ ISO 10993-11: 2017 Biological evaluation of medical devices - Part 23: Tests for systemic toxicity

7.3 Performance

- ✧ Optical performance testing was conducted on the Vathin® Video Bronchoscope System. The optical performance of the system complies with ISO8600 series.
- ✧ The performance test report of 6% (Luer) taper was tested according ISO 80369-7.
- ✧ Mechanical characteristics including the test leaking, bending, articulating bending angle, endurance of the bending section, radius of the bending section and irrigation tests were performed.
- ✧ Aging performance and sterile packaging integrity tests were also performed.

7.4 Software verification and validation

- ✧ FDA guidance: Content of Premarket Submissions for Device Software Functions

7.5 EO sterilization validation

- ISO 11135:2014+A1:2018 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 10993-7:2008+ A1:2019 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

7.6 Usability

- IEC 62366-1:2015 +A1:2020 Medical devices - Part 1: Application of usability engineering to medical devices

8 Conclusions

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