October 29, 2024

Hunan Vathin Medical Instrument Co., Ltd
Charlene Du
RA manager
1/F, Building 12, Innovation and Entrepreneurship Service Center
No 9 Chuanqi West Road, Jiuhua Economic Development Zone
Xiangtan, Hunan 411100
China

Re: K241612
Trade/Device Name: Video Bronchoscope System; Single-use Flexible Bronchoscope (BC-S1E00-L, BC-S1H00-L, BC-S1J00-L, BC-S1E00, BC-S1H00, BC-S1J00.); Digital Video Monitor (DVM-D1, DVM-D2)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: September 27, 2024
Received: September 27, 2024

Dear Charlene 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,

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

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)*

K241612

Device Name

Video Bronchoscope System:
Single-use Flexible Bronchoscope (BC-S1E00-L,BC-S1H00-L,BC-S1J00-L,BC-S1E00,BC-S1H00, BC-S1J00)
Digital Video Monitor (DVM-D1,DVM-D2)

Indications for Use *(Describe)*

The Single-use Flexible Bronchoscope has been designed to used with Vathin Display Units, endoscopic accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.
The Digital Video Monitor is specially designed to be used with Vathin medical endoscopes and other auxiliary equipment for the purposes of endoscopic diagnosis, treatment and video observation.
The Video Bronchoscope System is for use in professional Healthcare Facility Environment.

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

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:	Du Jing Title: Regulatory Affairs Manager Phone: +86-731-5558558 E-mail: charlene@vathin.com

II Device

Trade Name of Device:	Video Bronchoscope System Single-use Flexible Bronchoscope
Model:	BC-S1E00-L, BC-S1H00-L, BC-S1J00-L, BC-S1E00, BC-S1H00, BC-S1J00. Digital Video Monitor DVM-D1, DVM-D2
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

510 (k) Number	K210883	K223299
Device Name:	aScope 4 Broncho Regular Sampler Set 5.0/2.2 aScope 4 Broncho Large Sampler Set 5.8/2.8	Ambu® aView™ 2 Advance
Common Name:	Flexible Bronchoscope	Flexible Bronchoscope
Classification Name:	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	21 CFR 874.4680	21 CFR 874.4680
Regulatory Class:	II	II
Product Code:	EOQ	EOQ

IV Device description

The Video Bronchoscope System consists of a Single-use Flexible Bronchoscope to be introduced within the airways or tracheobronchial tree and a Digital Video Monitor for endoscopic image processing and displaying. The flexible bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. The Digital Video Monitor receives, processes the real-time image signal from the endoscope and displays the live image on the screen.

The Single-use Flexible Bronchoscope has six models: BC-S1E00-L, BC-S1H00-L, BC-S1J00-L, BC-S1E00, BC-S1H00, BC-S1J00. The main differences between product models are the size of the device channel, the color of the rotating sleeve, and whether it is self-locking.

V Indications for use

The Single-use Flexible Bronchoscope has been designed to be used with Vathin Display Units, endoscopic accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The Digital Video Monitor is specially designed to be used with compatible Vathin endoscopes and other auxiliary equipment for the purposes of endoscopic diagnosis, treatment and video observation.

The Video Bronchoscope System is for use in professional Healthcare Facility Environment.

VI Comparison of technological characteristics with the predicate devices

Intended use and principal operation, the technology, design and performance specifications of Video Bronchoscope system are either identical or substantially equivalent to existing legally marketed predicate devices. Any differences in various attributes as listed below between the Video Bronchoscope System 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 Digital Video Monitor	aScope 4 Broncho Regular Sampler Set 5.0/2.2 aScope 4 Broncho Large Sampler Set 5.8/2.8 Ambu® aView 2 Advance
Field of view (degree)	110°	85°
Direction of view (degree)	0°	0°
Depth of view	3-100mm	6-50mm
Bending angle (degree)	Up: 210° Down: 210°	aScope 4 Broncho Regular: Up: 180°, Down: 180° aScope 4 Broncho Large: Up: 180°, Down: 160°
Working length (mm)	600	600

Device feature	Proposed Device	Predicate Device
Trade Name	Single-use Flexible Bronchoscope Digital Video Monitor	aScope 4 Broncho Regular Sampler Set 5.0/2.2 aScope 4 Broncho Large Sampler Set 5.8/2.8 Ambu® aView 2 Advance
Digital video technology	CMOS	CMOS
Illumination source	LED	LED
Single-use	Yes	Yes
Biocompatibility	No Cytotoxicity	No Cytotoxicity
	No Irritation to Skin	No Irritation to Skin
	No significant evidence of sensitization	No significant evidence of sensitization
Sterilization	EO	EO
Single-use	Yes	Yes
Max. resolution	1920 * 1080	1920 * 1080
Display type	15.6"" touch screen	12.8” touch screen
USB connection	A-type	Type A
Video output	HDMI/SDI	HDMI/SDI
Image/Video capture	Yes	Yes

VII Summary of Non-clinical tests:

Biocompatibility testing

Biocompatibility of the Single-Use Flexible Bronchoscope was evaluated in accordance with ISO 10993-1:2018 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 has been validated according to ISO11135, which thereby routine control and monitoring parameters of the process has been determined. Shelf-life and package of single-use flexible video bronchoscope was validated.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Video Bronchoscope System. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Performance testing

The following performance tests was conducted on the Video Bronchoscope System:

- Optical tests: including color rendering index, illuminance, correlated color temperature, geometric distortion, color restoration, resolution, depth of field, field of view, direction of view, signal-to-noise ratio, dynamic range, geometric distortion, image brightness uniformity and field of view.
- Mechanical tests: working length, minimum instrument channel width, outer diameter of main hose, max. outer diameter, bending angle, water delivery capacity and attractive volume capacity test.
- Shelf-life verification test.

- Packaging verification test.
- Electromagnetic Compatibility according to IEC 60601-1-2
- Electrical Safety according to IEC 60601-1 and IEC 60601-2-18.

Result: All tests were passed.

VIII Conclusion

Based on the indication for use, technological characteristics, performance data and comparison to predicate device it has been concluded that the functionality and intended use of Video Bronchoscope System is substantially equivalent to the predicate device. It is concluded that Video Bronchoscope System is as safe and as effective and performs as well as the predicate device.