February 13, 2020

Hunan Vathin Medical Instrument Co., Ltd.
℅ Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
8-9th Floor, R&D Building, N0., 26 Qinglan Street
Panyu District
Guangzhou, 510006 China

Re: K191828
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: January 14, 2020
Received: January 16, 2020

Dear Mike Gu:

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,

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191828

Device Name
Vathin® Video Bronchoscope System

Indications for Use *(Describe)*
The Vathin®H-SteriScopeTM I Single-use flexible Video Bronchoscope have been designed to be used with the Vathin®VisionCenterTM I Digital Video Processor, 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.

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

Hunan Vathin Medical Instrument Co., Ltd.

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Phone: +86 18017856052

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Contact Person:	Yun Feng RA Hunan Vathin Medical Instrument Co., Ltd. Tel: +86 18017856052 Fax: +86 731 5555 8558
Date Prepared:	Feb 13, 2020

II. DEVICE

Name of Device:	Vathin® Video Bronchoscope System
Model:	Vathin®H-SteriScope™ I 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®VisionCenter™ I Digital Video Processor DVP-A1
Common or Usual Name:	Bronchoscope (flexible or rigid) and accessories

Classification Names:	Bronchoscope (flexible or rigid) and accessories (21 CFR 874.4680)
Regulation Class:	II
Product Code:	EOQ

III. PREDICATE DEVICE

Predicate device	K173727: Ambu® aScope™ 3 Slim 3.8/1.2 Ambu® aScope™ 3 Regular 5.0/2.2 Ambu® aScope™ 3 Large 5.8/2.8 Ambu® aScope™ 4 Broncho Slim 3.8/1.2 Ambu® aScope™ 4 Broncho Regular 5.0/2.2 Ambu® aScope™ 4 Broncho Large 5.8/2.8 Ambu® aView™ Monitor

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Vathin® Video Bronchoscope System consists of Vathin®H-SteriScope™ I Single-use flexible Video Bronchoscope (eighteen models shown in below) to be introduced within the airways or tracheobronchial tree and Vathin®VisionCenter™ I Digital Video Processor (model: DVP-A1) for clinical image processing. The Vathin®H-SteriScope™ I Single-use flexible bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. The Vathin®VisionCenter™ I Digital Video Processor provides power and processes the images for medical electronic endoscope.

Models of Vathin®H-SteriScope™ I Single-use flexible Video Bronchoscope

Bronchoscope zero:	BCV1-01/BCV1- 02
Bronchoscope slim 3.2/1.2:	BCV1-C1/BCV1-C2
Bronchoscope slim 4.1/1.7	BCV1-H1/BCV1-H2
Bronchoscope normal 4.7/2.0	BCV1-K1/BCV1-K2
Bronchoscope normal 4.9/2.2	BCV1-M1/BCV1-M2

Bronchoscope large 5.2/2.4	BCV1-O1/BCV1-O2
Bronchoscope large 5.8/2.8	BCV1-S1/BCV1-S2
Bronchoscope extra 6.0/3.0	BCV1-U1/BCV1-U2
Bronchoscope extra 6.2/3.2	BCV1-W1/BCV1-W2

Vathin®H-SteriScope™ I Single-use flexible Video Bronchoscope is a sterile single used flexible bronchoscope. Vathin®VisionCenter™ I Digital Video Processor is a reusable monitor.

The light emitted by the LED cold light source of the Vathin®H-SteriScope™ I Single-use flexible Video Bronchoscope lens is irradiated into the body cavity, and the light reflected from the cavity enters the optical system and is imaged on the CMOS (complementary metal oxide semiconductor). The CMOS acquisition image is controlled by the CMOS drive circuit, and the standard color video signal is output to the Vathin®VisionCenter™ I Digital Video Processor via the encoding circuit. The Vathin®VisionCenter™ I Digital Video Processor adjusts the brightness of the light source or corrects the image according to the video signal output from the CMOS, and outputs the corrected standard color video signal.

Vathin®H-SteriScope™ I Single-use flexible Video Bronchoscope has the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Flexible insertion cord
- Camera and LED light source at the distal tip
- Sterilized by Ethylene Oxide
- For single use

The differences between the Vathin®H-SteriScope™ I Single-use flexible Video Bronchoscope models are as follow:

- Presence or absence of working channel
- Working channel inner diameter
- Insertion tube outer diameter

- The length of insertion tube

Vathin®VisionCenter™ I Digital Video Processor has the following physical and performance characteristics:

- Provide image from Vathin®H-SteriScope™ I Single-use flexible Video Bronchoscope for observation
- Can connect to an external monitor
- Reusable device

V. INDICATION FOR USE

The Vathin®H-SteriScope™ I Single-use flexible Video Bronchoscope have been designed to be used with the Vathin®VisionCenter™ I Digital Video Processor, 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

This comparison of the specifications demonstrates the functional equivalence of the products.

Specification	Subject device	Predicate device	Remark
K Number	K191828	k173727	
Manufacturer	Hunan Vathin Medical Instrument Co., Ltd.	Ambu A/S	

Specification	Subject device	Predicate device	Remark
Model	Vathin®H-SteriScope™ I 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®VisionCenter™ I Digital Video Processor DVP-A1	Ambu® aScope™ 3 Slim 3.8/1.2 Ambu® aScope™ 3 Regular 5.0/2.2 Ambu® aScope™ 3 Large 5.8/2.8 Ambu® aView™ Monitor	
Device Trade name	Vathin® Video Bronchoscope System	Ambu® aScope™ 3 System	
Intended Use	The Vathin™ Single-use video endoscope have been designed to be used with the Vathin®VisionCenterTM I Digital Video Processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.	The aScope 3 endoscopes have been designed to be used with the aView monitor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.	Same
Working place/User	Use in a hospital environment by trained surgical physicians who are familiar with endoscopic procedures.	Use in a hospital environment by trained surgical physicians who are familiar with endoscopic procedures.	Same
Population	Adults	Adults	Same

Specification	Subject device	Predicate device	Remark
Technology	The Flexible bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. Anatomical images are transmitted to the user by the video processor with a CMOS chip at the distal end of the endoscope and the images showing on a monitor.	The Flexible bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. Anatomical images are transmitted to the user by the video processor with a CMOS chip at the distal end of the endoscope and the images showing on a monitor.	Same
Conical lock	6 % (Luer) taper	6 % (Luer) taper	Same
Performance	Complies with: ISO 8600	Complies with: ISO 8600	Same
Field of view (degree)	110°±5%	85°	Larger than the predicate device.
Direction of view (degree)	0	0	Same
Depth of view	3-30mm	8 – 19mm	Larger range than the predicate device.
Bending angle (degree)	Up: 210 Down: 210	Slime and Regular: Up: 130 Down: 130 Large: Up: 140 Down: 110	Larger range than the predicate device.
Endurance of the bending section	More than 2000 times, the maximum of 5000 times	More than 1000 times, the maximum of 1700 times	More endurance of bending times than the predicted device.
Radius of the bending section	Outer diameter about 2.2cm (Vathin® Video Bronchoscope BCV1-C1 3.2/1.2)	Outer diameter about 2.7cm (Ambu® aScope™ 3 Slim 3.8/1.2)	Thinner than the predicate device.
Distal end diameter(mm)	2.2/3.2/4.1/4.7/4.9/5.2/5.8/6.0/6.2	4.3/5.5/6.3	More specifications than predicted device.
Maximum insertion portion width(mm)	2.2/3.2/4.1/4.7/4.9/5.2/5.8/6.0/6.2	4.2/5.4/6.2	

Specification	Subject device	Predicate device	Remark
Minimum insertion channel width(mm)	0/1.2/1.7/2.0/2.2/2.4/2.8/3.0/3.2	1.2/2.0/2.6	
Working length (mm)	600/700	600	
Digital video technology	CMOS	CMOS	Same
Illumination source	LED	LED	Same
Shutter speed	1/30 sec~1/12000 sec	1/60 sec- 1/10000 sec	Faster than the predicate device.
White balance	Manual	Automatic	Different
Video format inputs (Camera)	RAW	analog signal RGB Bayer pattern	Different
Output formats	DVI/USB	Composite video	Different
Enhancement control (contrast and definition)	Yes	Yes	Same
Image/Video capture	Yes	Yes	Same
Storage	Yes SD Card	Yes SD Card	Same
Single-use	Yes	Yes	Same
Biocompatibility	No Cytotoxicity	No Cytotoxicity	Same
	No Irritation to Skin	No Irritation to Skin	Same
	No significant evidence of sensitization	No significant evidence of sensitization	Same
	No pyrogen	No pyrogen	Same
Sterilization	EO	EO	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the Vathin® Video Bronchoscope System was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The following tests were performed, as recommended:

- Cytotoxicity
- Irritation
- Pyrogen
- Sensitization

The Vathin® Video Bronchoscope Systems is considered surface – mucosal membrane contacting for a duration of less than 24 hours.

Sterilization and shelf life testing

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the Vathin®H-SteriScope™ I Single-use flexible Video Bronchoscope is validated.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Vathin® 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, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Bench performance testing

The following bench tests were performed:

1. Optical performance testing according to ISO8600 series.
2. The performance test of 6% (Luer) taper according ISO 80369-7.
3. 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 compared with the predicate device.
4. Color feature separation and photobiological safety test
5. Color performance (color reproduction), optical performance (resolution, depth of view and image intensity uniformity), SNR and dynamic test compared with the predicate device.

Clinical Testing

Based on the similarities of the device specifications, intended use, indications for use between the Vathin® Video Bronchoscope System and its predicate device, no clinical studies were needed to support this 510(k) Premarket Notification.

VIII. CONCLUSION

The Vathin® Video Bronchoscope System is substantially equivalent to the predicate device. The non-clinical testing demonstrates that the subject device is as safe, as effective and performs as well as the predicate device.