April 11, 2023

Shenzhen HugeMed Medical Technical Development Co., Ltd
% Kevin Wang
Consultant
Shenzhen Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K222910
Trade/Device Name: Bronchoscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: March 7, 2023
Received: March 8, 2023

Dear Kevin Wang:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222910

Device Name
Bronchoscope System

Indications for Use *(Describe)*

The Single-use Bronchoscope have been designed to be used with the Image Processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.
The Bronchoscope System is for use in a hospital environment. The Single-use Bronchoscope is a single-use device designed for use in adults.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2023/04/11

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang
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3. Subject Device Information

Trade/Device Name	Bronchoscope System
Model	Single-use Bronchoscope:BR-M58, BR-M52, BR-M50, BR-M40, BR-M32, BR-M22 Image Processor: VLM-02
Common Name	Bronchoscope System
Regulatory Class	Class II
Classification	21CFR 874.4680 / Bronchoscope (Flexible or Rigid) / EOQ
Submission type	Traditional 510(K)

4. Predicate Device

510(k) number: K173727
Product name: Ambu® aScope™ 3, Ambu® aView™ Monitor
Submitter: Ambu Inc.

5. Reference Device

510(k) number: K213782
Product name: Video Bronchoscope System
Submitter: Micro-Tech (Nanjing) Co., Lts

6. Device Description

The Bronchoscope System consists of Single-use Bronchoscope (six models shown in below) to be introduced within the airways or tracheobronchial tree and Image Processor (model: VLM-02) for clinical image processing. The Flexible Bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. The Image Processor provides power and processes the images for medical electronic endoscope.

System name	Component name	Model
Bronchoscope System	Single-use Bronchoscope	BR-M58, BR-M52, BR-M50, BR-M40, BR-M32, BR-M22
	Image Processor	VLM-02

The Single-use Bronchoscope is a sterile single used flexible bronchoscope. The Image Processor is a reusable monitor.

The light emitted by the LED cold light source at the distal tip of the Single-use Bronchoscope is irradiated into the body cavity, and the light reflected from the cavity enters the optical system and is captured by the CMOS image sensor. The CMOS acquisition image is controlled by the CMOS drive circuit, and the RGB video signal is output to the Image Processor via the VI circuit. The Image Processor receives video signals from the endoscope, processes the video signals, and outputs the processed video signal to the monitor. The Image Processor also controls the brightness of the LEDs on the endoscope.

The optical components and their arrangement at the distal tip for all models of the Single-use Bronchoscope are identical.

Single-use 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

Image Processor has the following physical and performance characteristics:

- Display the image from the Single-use Bronchoscope on the screen
- Can record screenshots or video of image from the Single-use Bronchoscope
- Can connect to an external monitor
- Reusable device

7. Intended use & Indication for use

The Single-use Bronchoscope have been designed to be used with the Image Processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways

and tracheobronchial tree.

The Bronchoscope System is for use in a hospital environment. The Single-use Bronchoscope is a single-use device designed for use in adults.

8. Comparison to the Predicate Device

Features	Subject Device	Predicate Device	Comparison
K number	K222910	K173727	/
Manufacturer	Shenzhen HugeMed Medical Technical Development Co., Ltd.	Ambu Inc.	/
Model	Single-use Bronchoscope:BR-M58, BR-M52, BR-M50, BR-M40, BR-M32, BR-M22 Image Processor: VLM-02	Ambu ® aScope™ 3 Broncho System: Ambu® aScope™ 3 Broncho Slim 3.8/1.2 Ambu® aScope™ 3 Broncho Regular 5.0/2.2 Ambu® aScope™ 3 Broncho Large 5.8/2.8 Ambu® aView™ Monitor	/
Classification Name	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories	/
Device trade name	Bronchoscope System	Ambu® aScope™ 3 Broncho Slim 3.8/1.2; Ambu® aScope™ 3 Broncho Regular 5.0/2.2; Ambu® aScope™ 3 Broncho Large 5.8/2.8; Ambu® aView Monitor	/
Product Code	EOQ	EOQ	Same
Indication for use	The Single-use Bronchoscope have been designed to be used with the Image Processor,	The aScope 3 Broncho endoscopes have been designed to be used with the aView monitor,	Same

Features	Subject Device	Predicate Device	Comparison
	endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The Bronchoscope System is for use in a hospital environment. The Single-use Bronchoscope is a single-use device designed for use in adults.	endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The aScope 3 system Broncho system are for use in a hospital environment. The aScope 3 Broncho are single-use devices designed for use in adults.	
Population	Adults	Adults	Same
Anatomic sites	airways and tracheobronchial tree	airways and tracheobronchial tree	Same
Rx only	Yes	Yes	Same
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
Connect to devices	Monitor	Monitor	Same
Performance	Complies with: ISO 8600	Complies with: ISO 8600	Same
Field of view (degree)	120°±10%	85°	Different
Direction of view (degree)	0°±10°	0°	Same

Features	Subject Device	Predicate Device	Comparison
Depth of view	3-50mm	8-19 mm	Different
Working length (mm)	600mm±10%	600mm	Same
Maximum insertion portion width	BR-M22: 2.2±10%mm BR-M32: 3.2±10%mm BR-M40: 4.4±10%mm BR-M50: 5.0±10%mm BR-M52: 5.2±10%mm BR-M58: 5.8±10%mm	aScope™ 3 Slim 4.3mm aScope™ 3 Regular 5.5mm aScope™ 3 Large 6.3mm	Different
Minimum instrument channel width	BR-M22: not applicable BR-M32: 1.2mm BR-M40: ≥1.1mm BR-M50: 2.8mm BR-M52: ≥2.1mm BR-M58: ≥2.5mm	aScope™ 3 Slim 1.2mm aScope™ 3 Regular 2.2mm aScope™ 3 Large 2.8mm	Different
Luer/Luer lock connection to working channel	No	Yes	Same as K213782 reference device without the luer lock connection
Deflection angle	180° upward and 180° downward	aScope™ 3 Slim: 130°up 130°down aScope™ 3 Regular: 150°up 130°down aScope™ 3 Large: 140°up 110°down	Same as K213782 reference device with the 180° deflection angle
Digital video technology	CMOS	CMOS	Same
Illumination source	LED	LED	Same
Separate monitor	Yes	Yes	Same
Energy used/power source	Yes	Yes	Same
Image/Video capture	Yes	Yes	Same

Features	Subject Device	Predicate Device	Comparison
Storage	Yes SD Card	Yes SD Card	Same
Disposable after use	Single-use Bronchoscope: Yes	aScope™ 3: Yes	Same
	Image Processor: Reusable	aView™: Reusable	Same
Components in contact with the patient is delivered sterile	Yes, EO	Yes, EO	Same
Suction possible	Yes	Yes	Same
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	Same
Shelf life	Single-use Bronchoscope: 3 Years Comply with ASTM F1980-16	aScope™ 3: 3 Years Comply with ASTM F1980-16	Same
Electrical Performance	Comply with ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009(R)2012 and A2: 2010/(R)2012 IEC 60601-1-2: 2014 IEC 60601-2-18:2009	Comply with ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009(R)2012 and A2: 2010/(R)2012 IEC 60601-1-2: 2014 IEC 60601-2-18:2009	Same

9. Performance Data

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

Biocompatibility testing

Biocompatibility of the Single-use Bronchoscope 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
- Sensitization

- Intradermal reactivity

The Single-use Bronchoscope is considered surface – mucosal membrane contacting for a duration of less than 24 hours.

Sterilization and shelf life testing

The Single-use Bronchoscope is provided sterile and its shelf-life is 3 years. Sterilization Process has been validated in accordance with ISO 11135:2014.
EO/ECH residual test was performed according to ISO 10993-7:2008.
The shelf life is determined based on optical testing and product performance testing after accelerated aging test according to ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and ASTM F1886/F1886M-16, ASTM F88/F88M-15, ASTM F 1929-15.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the 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 ISO 8600 series.
2. Color performance (color reproduction), geometric distortion, optical performance (resolution, depth of field and image intensity uniformity), SNR and dynamic range, image frame frequency and system delay test compared with the predicate device.
3. Mechanical testings including suction and bending testing.

10. Clinical study

No clinical study is included in this submission

11. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.