November 24, 2021

Shanghai AnQing Medical Instrument CO., Ltd.
% Olivia Meng
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd
9th Floor, R&D Building, No. 26 Qinglan Street,
Panyu District
Guangzhou, 510006
China

Re: K211169
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: October 27, 2021
Received: October 29, 2021

Dear Olivia Meng:

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,

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)*
K211169

Device Name
Bronchoscope System

Indications for Use *(Describe)*
The flexible bronchoscope have been designed to be used with the video 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 Flexible 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

I. SUBMITTER

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Secondary contact person:	Shuwen Fan RA Manager Shanghai AnQing Medical Instrument Co., Ltd. Tel: +86-021-61117375 Fax: +86-021-61117374
Date Prepared:	April 6, 2021

II. DEVICE

Name of Device:	Bronchoscope System
Model:	Flexible Bronchoscope: BS41H-12EU, BS41H-12US, BS46H-17EU, BS46H-17US, BS50H-20EU, BS50H-20US, BS53H-22EU, BS53H-22US, BS55H-24EU, BS55H-24US, BS59H-28EU, BS59H-28US Video Processor: EOS-H-01
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 Bronchoscope System consists of Flexible Bronchoscope (twelve models shown in below) to be introduced within the airways or tracheobronchial tree and Video Processor (model: EOS-H-01) for clinical image processing. The Flexible Bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. The Video Processor provides power and processes the images for medical electronic endoscope.

Models of Flexible Bronchoscope

BS41H-12EU	BS41H-12US
BS46H-17EU	BS46H-17US
BS50H-20EU	BS50H-20US
BS53H-22EU	BS53H-22US
BS55H-24EU	BS55H-24US
BS59H-28EU	BS59H-28US

The Flexible Bronchoscope is a sterile single used flexible bronchoscope. The Video Processor is a reusable monitor.

The light emitted by the LED cold light source at the distal tip of the disposable video 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 Video Processor via the VI circuit. The Video Processor receives video signals from the endoscope, processes the video signals, and outputs the processed video signal to the attached monitor. The video processor also controls the brightness of the LEDs on the endoscope.

Flexible 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

Video Processor has the following physical and performance characteristics:

- Provide image from Flexible Bronchoscope for observation
- Can connect to an external monitor
- Reusable device

V. INDICATION FOR USE

The flexible bronchoscope have been designed to be used with the video 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 Flexible Bronchoscope is a single-use device designed for use in adults.

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	--	K173727	
Manufacturer	Shanghai AnQing Medical Instrument Co., Ltd.	Ambu A/S	
Model	Flexible Bronchoscope: BS41H-12EU, BS41H-12US, BS46H-17EU, BS46H-17US, BS50H-20EU, BS50H-20US, BS53H-22EU, BS53H-22US, BS55H-24EU, BS55H-24US, BS59H-28EU, BS59H-28US Video Processor: EOS-H-01	Ambu ® aScope™ 4 Broncho System: 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	
Classification Name	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories	
Device Trade name	Bronchoscope System	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	
Product Code	EOQ	EOQ	Same
Intended Use	The flexible bronchoscopes have been designed to be used with the video 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 Flexible Bronchoscope is a single-use device designed for use in adults.	The aScope 4 Broncho 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. The aScope 4 Broncho system are for use in a hospital environment. The aScope 4 Broncho is a single-use device designed for use in adults.	Same

Specification	Subject device	Predicate device	Remark
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
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°±10%	85°	Larger than the predicate device.
Direction of view (degree)	0°±3°	0°	Same
Depth of view	5-100mm	6 – 50mm	Larger range than the predicate device.
Working length (mm)	620 mm±3%	600	Longer than the predicate device.
Digital video technology	CMOS	CMOS	Same
Illumination source	LED	LED	Same
Image/Video capture	Yes	Yes	Same
Storage	Yes USB storage	Yes SD Card	Similar
Single-use	Yes	Yes	Same
Biocompatibility	No Cytotoxicity	No Cytotoxicity	Same

Specification	Subject device	Predicate device	Remark
	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 Flexible 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
- Intracutaneous reactivity
- Material-Mediated Pyrogenicity
- Acute systemic toxicity

The Flexible Bronchoscope 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 Flexible Bronchoscope is validated.

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. Mechanical characteristics were performed compared with the predicate device.
3. Color feature separation and photobiological safety test.
4. 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 Bronchoscope System and its predicate device, no clinical studies were needed to support this 510(k) Premarket Notification.

VIII. CONCLUSION

The 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.