July 8, 2022

Micro-Tech (Nanjing) Co., Lts
Sally He
RA Engineer
No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial
Development Zone
Nanjing, Jiangsu Province 210032
China

Re: K213782
Trade/Device Name: 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 2, 2022
Received: June 6, 2022

Dear Sally He:

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)*
K213782

Device Name
Video Bronchoscope System

Indications for Use *(Describe)*
The Single-Use Video Bronchoscopes have been designed to be used with the Digital Controller, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.
The Single-Use Video Bronchoscope is only designed for use in hospitals.
The Single-Use Video Bronchoscope is a disposable medical device for use on adults.

The Digital Controller can be used in conjunction with Micro-Tech scope products to provide illumination brightness adjustment ability and receive, process and output images from them for endoscopy.

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.

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510K Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: **K213782**

1. Date of Preparation: 2022-07-08

2. Sponsor Identification

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, PRC

Establishment Registration Number: 3004837686

Contact Person: Sally He

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Email: RA.Micro-Tech@outlook.com

3. Identification of Proposed Device

Trade Name: Single-Use Video Bronchoscope, Digital Controller

Common Name: Video Bronchoscope System

Regulatory Information

Device Classification Name: Bronchoscope (Flexible)

Classification: 2

Product Code: EOQ

Regulation Number: 21 CFR 874.4680

Review Panel: Ear Nose & Throat

4. Identification of Predicate Device

510(k) Number: K173727

Product Name: Ambu® aScope™ 3, Ambu® aView™ Monitor

Manufacturer: Ambu Inc.

5. Indications for Use

The Single-Use Video Bronchoscopes have been designed to be used with the Digital Controller, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The Single-Use Video Bronchoscope is only designed for use in hospitals.

The Single-Use Video Bronchoscope is a disposable medical device for use on adults.

The Digital Controller can be used in conjunction with Micro-Tech scope products to provide illumination brightness adjustment ability and receive, process and output images from them for endoscopy.

6. Device Description

The Video Bronchoscope System consists of:

Single-Use Video Bronchoscope:

- SVB11001
- SVB22001
- SVB33001

Digital Controller:

- DC00001

The Single-Use Video Bronchoscopes are all sterile single use flexible bronchoscope and Digital Controller is a reusable device.

The Single-Use Video Bronchoscopes have the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Flexible insertion cord
- Working channel
- Camera and LED light source at the distal tip.

The light emitted by the LED cold light source of the Single-Use Video Bronchoscopes lens is irradiated into the body cavity, and the light reflected from the cavity enters the optical system and is imaged on the CMOS. The CMOS acquisition image is controlled by the CMOS drive circuit, and the standard color video signal is output to the digital video processor via the encoding circuit. The digital video processor adjusts the brightness of the light source and outputs the standard color video signal. The imaging sensor pixel count is 400× 400 and the pixel size is 1.75 μm × 1.75 μm.

The optical components and their arrangement at the distal tip for all models of Single-Use Video Bronchoscopes are identical.

The Single-Use Video Bronchoscopes have different size as follows:

- Maximum insertion portion width
- Deflection angle
- Minimum instrument channel width

The Digital Controller has the following physical and performance characteristics:

- Displays the image from The Single-Use Video Bronchoscope on the screen
- Can record screenshots or video of image from the Single-Use Video Bronchoscope
- Can connect to an external monitor
- Reusable device

7. Comparison of Technological Characteristics

The **Video Bronchoscope System** substantially equivalent device materials, design, configuration, packaging, sterilization process and intended use as those featured in the predicate device **Ambu® aScope™ 3, Ambu® aView™ Monitor** (K173727).

Comparison to predicate Devices:

Characteristics	**Proposed Device** **Single-Use Video Bronchoscope, Digital Controller**	**Predicated Device** **Ambu® aScope™ 3, Ambu® aView™ Monitor (K173727)**	**Remark**
Product Code	EOQ	EOQ	Same
Class	II	II	Same
Regulation Description	Bronchoscopes (flexible or rigid) and accessories	Bronchoscopes (flexible or rigid) and accessories	Same

Characteristics	Proposed Device Single-Use Video Bronchoscope, Digital Controller	Predicated Device Ambu® aScope™ 3, Ambu® aView™ Monitor (K173727)	Remark
Regulation number	874.4680	874.4680	Same
Indications for Use	The Single-Use Video Bronchoscopes have been designed to be used with the Digital Controller, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The Single-Use Video Bronchoscope is only designed for use in hospitals. The Single-Use Video Bronchoscope is a disposable medical device for use on adults. The Digital Controller can be used in conjunction with Micro-Tech scope products to provide illumination brightness adjustment ability and receive, process and output images from them for endoscopy.	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 The aScope 3™ system is for use in a hospital environment The aScope 3™ is single-use devices designed for use in adults.	Same
Compatible device specification	They have been evaluated for used with the endotracheal tubes (ETT), double lumen tubes (DLT) and endoscopic accessories (EA).	They have been evaluated for used with the endotracheal tubes (ETT), double lumen tubes (DLT) and endoscopic accessories (EA).	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
Performance	Complies with ISO 8600	Complies with ISO 8600	Same
Light source	LED	LED	Same
Separate monitor	Yes	Yes	Same
Energy used/Power source	Yes	Yes	Same

Characteristics	Proposed Device Single-Use Video Bronchoscope, Digital Controller		Predicated Device Ambu® aScope™ 3, Ambu® aView™ Monitor (K173727)		Remark
Images by camera technology	Yes		Yes		Same
Components in contact with the patient is delivered sterile	Yes		Yes		Same
Disposable after use	Single-Use Video Bronchoscope	Yes	aScope 3™	Yes	Same
	Digital Controller	Reusable	aView™ Monitor	Reusable	
Connect to devices	Monitor		Monitor		Same
Anatomic sites	Airways and tracheobronchial tree		Airways and tracheobronchial tree		Same
Target population	Adults		Adults		Same
Rx-only	Yes		Yes		Same
Design concept	Portable		Portable		Same
Working length	600mm		600mm		Same
Maximum insertion portion width	SVB11001 4.4mm SVB22001 5.5mm SVB33001 6.3mm		aScope™ 3 Slim 4.3mm aScope™ 3 Regular 5.5mm aScope™ 3 Large 6.3mm		Similar
Minimum instrument channel width	SVB11001 1.2mm SVB22001 2.2mm SVB33001 2.8mm		aScope™ 3 Slim 1.2mm aScope™ 3 Regular 2.2mm aScope™ 3 Large 2.8mm		Same
Luer/Luer lock connection to working channel	No		Yes		Different
Deflection angle	SVB11001	180 °up 180 °down	aScope™ 3 Slim	130 °up 130 °down	Different
	SVB22001		aScope™ 3 Regular	150 °up 130 °down	
	SVB33001		aScope™ 3 Large	140 °up 110 °down	
Field of view	120 °		85 °		Different

Characteristics	Proposed Device Single-Use Video Bronchoscope, Digital Controller	Predicated Device Ambu® aScope™ 3, Ambu® aView™ Monitor (K173727)	Remark
Depth of view	5mm-50mm	8mm-19mm	Different
Suction possible	Yes	Yes	Same
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	Same
Shelf Life	Single-Use Video Bronchoscope: 1 Year Comply with ASTM F1980-16	aScope™ 3: 3 Years Comply with ASTM F1980-16	Different
Electrical Performance	Comply with ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 IEC60601-1-2:2014 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 IEC60601-1-2:2014 IEC 60601-2-18:2009	Same
Software	Comply with IEC 62304:2015	Comply with IEC 62304:2015	Same
Labeling	Conforms to 21 CFR part 801	Conforms to 21 CFR part 801	Same

8. Performance Data

Performance testing was conducted to demonstrate the essential performance of the proposed device **Video Bronchoscope System** and confirmed that the proposed device works as intended with the compatible devices.

The bench tests below were tested and evaluated as substantially equivalent to the predicate device.

- Dimension
- Deflection angle
- Bending radius
- Endurance test
- Control lever rotation torque
- Connection strength
- Suction at full bend condition
- Liquid injection
- Matching test with Digital Controller

The optical tests below were tested and evaluated as substantially equivalent to the predicate device.

- Field of view
- Direction of View
- Dynamic Range
- Signal-to-noise ratio (SNR)
- Resolution
- Depth of Field
- Photobiological Safety
- Geometric Distortion
- Image Intensity Uniformity
- Color Performance

Shelf-life testing was conducted based on an accelerated aging test in accordance with ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. One-year aging test was performed to demonstrate longer stability and support the results of the accelerated aging test.

Sterilization validation was carried out in accordance with ISO 11135:2014 “Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”.

Biocompatibility testing was performed 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".

Electrical performance was performed in accordance with ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”, IEC 60601-2-18:2009 “Medical

electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment", IEC 60601-1-2:2014 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"

9. Animal Study

No animal study is included in this submission.

10. Clinical Study

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the **Video Bronchoscope System** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device under **K173727.**