August 11, 2025

Zhejiang UE Medical Corp.
℅ Jie Yang
Consultant
Chonconn Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong
China

Re: K251823
Trade/Device Name: UE BRONCHO Single-Use Bronchoscopes (EBS-380C); UE BRONCHO Single-Use Bronchoscopes (EBS-500C); UE BRONCHO Single-Use Bronchoscopes (EBS-600C); UE Display (UE-M10S)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: June 13, 2025
Received: June 13, 2025

Dear Jie Yang:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251823

Please provide the device trade name(s).

UE BRONCHO Single-Use Bronchoscopes (EBS-380C);
UE BRONCHO Single-Use Bronchoscopes (EBS-500C);
UE BRONCHO Single-Use Bronchoscopes (EBS-600C);
UE Display (UE-M10S)

Please provide your Indications for Use below.

UE BRONCHO Single-Use Bronchoscope:
The UE BRONCHO Single-Use Bronchoscopes has been designed to be used with the UE Display, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.
The UE BRONCHO Single-Use Bronchoscopes is for use in a hospital environment.
The UE BRONCHO Single-Use Bronchoscopes is single-use device designed for use in adults.

UE Display:
The UE Display is reusable digital monitor, intended to display live imaging data from UE Medical visualization devices.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2025/6/13

1. Submission sponsor

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2. Submission correspondent

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Contact person: Yang Jie
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3. Subject Device Information

Trade/Device Name	UE BRONCHO Single-Use Bronchoscopes, UE Display
Model	UE BRONCHO Single-Use Bronchoscopes (EBS-380C); UE BRONCHO Single-Use Bronchoscopes (EBS-500C); UE BRONCHO Single-Use Bronchoscopes (EBS-600C); UE Display (UE-M10S)
Common Name	Endoscope and accessories
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™ 4 Broncho, Ambu® aView™ Monitor
Product code: EOQ

5. Device Description

The bronchoscope system consists of UE BRONCHO Single-Use Bronchoscopes and UE Display. The UE BRONCHO Single-Use Bronchoscopes (the bronchoscopes) are sterile,

single-use flexible video bronchoscopes available in three sizes (Slim, Regular, Large). The bronchoscopes have been designed to be used with the UE Display (reusable, non-sterile), endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The bronchoscope system is designed for use by adults in a hospital environment.

6. Intended use & Indication for use

UE BRONCHO Single-Use Bronchoscope:

The UE BRONCHO Single-Use Bronchoscopes has been designed to be used with the UE Display, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The UE BRONCHO Single-Use Bronchoscopes is for use in a hospital environment.

The UE BRONCHO Single-Use Bronchoscopes is single-use device designed for use in adults.

UE Display:

The UE Display is reusable digital monitor, intended to display live imaging data from UE Medical visualization devices.

7. Comparison to the Predicate Device

Features	Subject Device	Predicate Device	Comparison
K number	K251823	K173727	/
Manufacturer	Zhejiang UE Medical Corp.	Ambu Inc.	/
Model	UE BRONCHO Single-Use Bronchoscopes, model EBS-380C, EBS-500C, EBS-600C UE Display, model UE-M10S.	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	UE BRONCHO Single-Use Bronchoscopes, model EBS-380C, EBS-500C,	Ambu® aScope™ 4 Broncho Slim 3.8/1.2; Ambu®	/

Features	Subject Device	Predicate Device	Comparison
	EBS-600C UE Display, model UE-M10S.	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
Indication for use	The UE BRONCHO Single-Use Bronchoscopes has been designed to be used with the UE Display, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The UE BRONCHO Single-Use Bronchoscopes is for use in a hospital environment. The UE BRONCHO Single-Use Bronchoscopes is single-use device designed for use in adults. UE Display: The UE Display is reusable digital monitor, intended to display live imaging data from UE Medical visualization devices.	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 are single-use devices designed for use in adults.	Same
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	The Flexible bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy.	Same

Features	Subject Device	Predicate Device	Comparison
	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.	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.	
Performance	Complies with: ISO 8600	Complies with: ISO 8600	Same
Field of view (degree)	90°	85°	Similar
Direction of view (degree)	0°	0°	Same
Depth of view	6-50 mm	6-50 mm	Same
Working length (mm)	600 mm	600mm	Same
Deflection angle	180° up, 180° down	Slim: 180° up, 180° down Regular: 180° up, 180° down Large: 180° up, 160° down	Same
Insertion Tube Outer Diameter	EBS-380C: 3.8 mm EBS-500C: 5.0 mm EBS-600C: 5.8 mm	Slim: 3.8 mm Regular: 5.0 mm Large: 5.8 mm	Same
Insertion Portion Maximum Diameter	EBS-380C: 4.4 mm EBS-500C: 5.5 mm EBS-600C: 6.5 mm	Slim: 4.3 mm Regular: 5.5 mm Large: 6.3 mm	Equivalent
Minimum Working Channel Diameter	EBS-380C: 1.15 mm EBS-500C: 2.15 mm EBS-600C: 2.75 mm	Slim: 1.2 mm Regular: 2.0 mm Large: 2.6 mm	Equivalent
Average Working Channel Diameter	EBS-380C: 1.2 mm EBS-500C: 2.2 mm EBS-600C: 2.8 mm	Slim: 1.2 mm Regular: 2.2 mm Large: 2.8 mm	Same

Features	Subject Device	Predicate Device	Comparison
Minimum ETT Inner Diameter Size	EBS-380C: 5.0 mm EBS-500C: 6.0 mm EBS-600C: 7.0 mm	Slim: 5.0 mm Regular: 6.0 mm Large: 7.0 mm	Same
Minimum DLT Inner Diameter Size	EBS-380C: 35 Fr EBS-500C: N/A EBS-600C: N/A	Slim: 35 Fr Regular: 41 Fr Large: N/A	Similar
Light Source	LED	LED	Same
Sterilization	EO	EO	Same
Imaging Sensor	CMOS	CMOS	Same
Single-Use	Yes	Yes	Same
Image Display	Displays image on a reusable video monitor (UE Display)	Displays image on a reusable video monitor (aView™ Monitor)	Same
Maximum resolution	1920*1200	800 x 480	Different
Display Size	10.1"	8.5"	Similar
Display Type	10.1" color TFT LCD	8.5" color TFT LCD	Similar
Brightness control	Yes	Yes	Same
Contrast control	Yes	Yes	Same
Storage Capacity	128 GB	8 GB	Different
Display-Operating Environment	5 - 40°C	10 - 40°C	Similar
	≤85%	30 - 85%	Similar
	860hPa ~ 1060hPa	800 - 1090 hPa	Similar
Dimensions (W x H x D)	257 mm x 195 mm x 36.2 mm	241 mm x 175 mm x 33.5 mm	Similar
Weight	1.50 kg	1.50 kg	Same
Battery Type	Lithium battery	Lithium battery	Same

8. Non-clinical Data

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

Biocompatibility testing

Biocompatibility of the UE BRONCHO Single-Use Bronchoscopes 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.

Sterilization and shelf life testing

The UE BRONCHO Single-Use Bronchoscopes are provided sterile, and its shelf-life is 3 years.

Sterilization Process has been validated accordance with ISO 11135:2014.

EO/ECH residual test was performed according to ISO 10993-7.

The shelf life is determined based on optical testing and product performance testing after accelerated aging test according to ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Package validation was conducted according to ISO 11607-1 and ISO 11607-2.

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, “Content of Premarket Submissions for Device Software Functions”.

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), Noise and dynamic range, Frame rate compared with the predicate device.

9. Clinical study

Not applicable.

10. Conclusion

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