June 16, 2022

OTU Medical Inc.
% Mingzi Hussey
Regulatory Consultant
Zi-medical
93 Springs Rd
Bedford, Massachusetts 01730

Re: K220399
Trade/Device Name: WiScope Digital Bronchoscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: May 11, 2022
Received: May 11, 2022

Dear Mingzi Hussey:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K220399

Device Name
WiScope® Digital Bronchoscope System

Indications for Use *(Describe)*
WiScope® Digital Bronchoscope System is designed for physicians to access, visualize, and perform endoscopy and endotherapy in the airways and tracheobronchial tree.

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

[As required by 21 CFR 807.92]

1. Submission Sponsor

OTU Medical Inc.
2231A Fortune Drive, San Jose, CA 95131
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Contact: Geping Liu
Email: info@otumed.com

2. Submission Correspondent

Mingzi Hussey
Zi-medical, Inc.
Address: 93 Springs Rd, Bedford, MA 01730 US
Phone: 206-981-0675
Email: mingzi@zi-medical.com

3. Date Prepared

June 16th, 2022

4. Device Identification

Trade Name: WiScope® Digital Bronchoscope System
Common Name/Classification Name: Bronchoscope (Flexible or Rigid) and accessories
Product Code: EOQ
Regulation Number: 21 CFR 874.4680
Regulation Class: Class II
Review Panel: Ear Nose & Throat
510(k) Number: K220399

5. Predicate Devices

The proposed devices are substantially equivalent to the following predicate devices:

Applicant	Device name	510(k) Number	Product code
Ambu Inc.	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	K173727	EOQ

6. Device Description

WiScope® Digital Bronchoscope System is designed for physicians to access, visualize, and perform endoscopy and endotherapy in the airways and tracheobronchial tree. This

system includes a single-use digital bronchoscope and an image system.

- The image system OTU-A is the currently marketed in the United States by OTU Medical Inc. under 510(k) # K181977.
- The single-use bronchoscope is comprised of a control body with an articulation lever, a suction connector, a suction button, and a working channel port, and a flexible insertion tube with an on-tip camera module and LED lighting source.

7. Indication for Use Statement

The subject device: WiScope® Digital Bronchoscope System is designed for physicians to access, visualize, and perform endoscopy and endotherapy in the airways and tracheobronchial tree.

The predicate device: 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. They have been evaluated for the following endotracheal tubes (ETT), double lumen tubes (DLT) and endoscopic accessories (EA) sizes:

	Minimum ETT inner diameter	Minimum DLT size	EA minimum working channel width
aScope 4 Broncho Slim	5.0mm	35Fr	Up to 1.2 mm
aScope 4 Broncho Regular	6.0mm	41Fr	Up to 2.0 mm
aScope 4 Broncho Large	7.0 mm	-	Up to 2.6mm

WiScope® Digital Bronchoscope System and the primary predicate device are similar in terms of indication for use. WiScope® Digital Bronchoscope System is used in the airways and tracheobronchial tree, while predicate device is used within the airways and tracheobronchial tree. They are all for endoscopy and endotherapy procedures with endoscopic accessories.

8. Comparison of Technological Characteristics

The following table compares the proposed device with the predicate devices in terms of intended use, technological characteristics and principles of operation, and it provides detailed information for determining substantial equivalences.

Table 5A – General Comparison

ITEM	Proposed Device	Predicate Device

<table>
<tr><td>Trade name</td><td>WiScope® Digital Bronchoscope System,
OTU-BR01,
OTU- BR02,
OTU-BR03,
OTU-A image system.</td><td>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</td></tr>
<tr><td>510(K) Submitter</td><td>OTU Medical Inc.</td><td>Ambu Inc.</td></tr>
<tr><td>510(K) Number</td><td>K220399</td><td>K173727</td></tr>
<tr><td>Classification Regulation</td><td>21 CFR 874.4680</td><td>21 CFR 874.4680</td></tr>
<tr><td>Classification and Code</td><td>Class II,
EOQ</td><td>Class II,
EOQ</td></tr>
<tr><td>Common name</td><td>Bronchoscope (Flexible or Rigid) and Accessories</td><td>Bronchoscope (Flexible or Rigid) and Accessories</td></tr>
<tr><td>Bronchoscope</td><td>Single-Use</td><td>Single-Use</td></tr>
<tr><td>Indications for Use</td><td>WiScope® Digital Bronchoscope System is designed for physicians to access, visualize, and perform endoscopy and endotherapy in the airways and tracheobronchial tree.</td><td>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. They have been evaluated for the following endotracheal tubes (ETT), double lumen tubes (DLT) and endoscopic accessories (EA) sizes:
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<tr><td>aScope 4 Broncho Large</td><td>7.0 mm</td><td>-</td><td>Up to 2.6mm</td></tr>
</table></td></tr>
<tr><td>Digital video technology</td><td>CMOS</td><td>CMOS</td></tr>
<tr><td>Illumination</td><td>LED</td><td>LED</td></tr>
<tr><td>Field of View (Diagonal)</td><td>100°</td><td>85°</td></tr>
</table>

Working Length (mm)	600mm	600mm
Maximum diameter of insertion portion	OTU-BR01: 9.5Fr(3.25mm)	1. aScope 4 Broncho Slim:4.3mm
	OTU-BR02: 16Fr(5.4mm)	2.aScope 4 Broncho Regular:5.5mm
	OTU-BR03: 18.6Fr(6.2mm)	3.aScope 4 Broncho Large:6.3mm
Insertion tube outer diameter	OTU-BR01: 2.85mm (8.6Fr)	1. aScope 4 Broncho Slim:3.8mm
	OTU-BR02: 5.1mm(15.3Fr)	2.aScope 4 Broncho Regular:5.0mm
	OTU-BR03: 5.9mm(17.7Fr)	3.aScope 4 Broncho Large:5.8mm
Working Channel Diameter	OTU-BR01: 3.6Fr(1.2mm)	1.aScope 4 Broncho Slim:1.2mm
	OTU-BR02: 6.6Fr(2.2mm)	2.aScope 4 Broncho Regular:2.0 mm
	OTU-BR03: 8.4Fr(2.8mm)	3.aScope 4 Broncho Large:2.6 mm
Up/Down Deflection	UP: 180° DOWN: 180°	1.aScope 4 Broncho Slim and aScope 4 Broncho Regular: UP: 180°DOWN: 180° 2.aScope 4 Broncho Large: UP: 180°DOWN: 160°
Direction of View	0°	0°
Brightness Control	Yes	Yes
White Balance	Yes	Yes
Output Formats	USB/AV/HDMI	USB/HDMI
Image/Video Capture	No	Yes
Sterilization	EO SAL: 10^{-6}	EO SAL: 10^{-6}
Packaging	WiScope® Single-Use Digital Flexible Bronchoscope is packaged by paper-plastic bag.	Ambu® aScope™ 4 Broncho is packaged by paper-plastic bag.
Label and Labeling	Meet FDA's Requirements	Meet FDA's Requirements
Safety Testing	*AAMI / ANSI ES60601-1:2012 *AAMI / ANSI / IEC 60601-1-2:2014 *IEC 60601-2-18:2009 *AAMI / ANSI / ISO 10993-5:2009 *ISO 10993-10:2010 *ISO 11135:2014 *ISO 10993-7:2008 *ISO 11607-1:2019 *ASTM F1980-16 *ISO 11737-2:2019 *ASTM D3078-2013 *ASTM F1929-15 *DIN 58953-6:2016	*IEC 60601-1:2012 *IEC 60601-2-18:2009 *ISO 8600-1-2015 *ISO 8600-3-1997 *ISO 8600-4-2014 *IEC 60601-1-2:2014 *ISO 10993-1:2009 *ISO 594-1:1986

	*ASTM F88/F88M-15 *ISO 8600-1-2015 *ISO 8600-3-2019 *ISO 8600-4-2014 *ISO 8600-6-2005 *ISO 594-1:1986	
Cytotoxicity	Comply with ISO 10993-5, no cytotoxicity effect	Comply with ISO 10993-1.
Irritation	Comply with ISO 10993-10, not an irritant	
Sensitization	Comply with ISO 10993-10, not a sensitizer.	

WiScope® Single-Use Digital Flexible Bronchoscope has three models:
OTU-BR01, with slim size insertion tube (8.6Fr),
OTU-BR02, with regular size insertion tube(15.3Fr),
OTU-BR03, with large size insertion tube(17.7Fr).

The proposed device shares the similar indications for use, same device operation, and overall technical and functional capabilities as the predicate device. It also has the same standards and requirements as the predicate device.

9. Description of Non-clinical Testing

The non-clinical tests of the subject device and predicate device are in compliance with the following standards and guidance.

ITEM	Proposed Device	Primary Predicate Device
Trade name	WiScope® Digital Bronchoscope System, OTU-BR01, OTU- BR02, OTU-BR03, OTU-A image 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
Safety Testing	*AAMI / ANSI ES60601-1:2012 *AAMI / ANSI / IEC 60601-1-2:2014 *IEC 60601-2-18:2009 *AAMI / ANSI / ISO 10993-5:2009 *ISO 10993-10:2010 *ISO 11135:2014 *ISO 10993-7:2008 *ISO 11607-1:2019 *ASTM F1980-16 *ISO 11737-2:2019 *ASTM D3078-2013 *ASTM F1929-15	*IEC 60601-1:2012 *IEC 60601-2-18:2009 *ISO 8600-1-2015 *ISO 8600-3-1997 *ISO 8600-4-2014 *IEC 60601-1-2:2014 *ISO 10993-1:2009 *ISO 594-1:1986

	*DIN 58953-6:2016 *ASTM F88/F88M-15 *ISO 8600-1-2015 *ISO 8600-3-2019 *ISO 8600-4-2014 *ISO 8600-6-2005 *ISO 594-1:1986	

WiScope® Digital Bronchoscope System has been verified for its safety and effectivity based on the following performance data. These tests only used to evaluate non-clinical testing of the subject device.

Electrical safety of the system was evaluated in accordance with IEC 60601-1and IEC 60601-2-18.
Electromagnetic compatibility was evaluated in accordance with IEC 60601-1-2.
All evaluation acceptance criteria were met.

The biocompatibility evaluation for WiScope® Single-Use Digital Flexible Bronchoscope was conducted in accordance with ISO 10993-1.
• Cytotoxicity (ISO 10993-5)
• Sensitization (ISO 10993-10)
• Intracutaneous reactivity test (ISO 10993-10)
Result: All tests were passed.

Shelf life for WiScope® Single-Use Digital Flexible Bronchoscope test is conducted based on ASTM F1980:
• Performance test
• Sterile Packaging Integrity
Result: All tests were passed.

Sterile barrier systems for WiScope® Single-Use Digital Flexible Bronchoscope were evaluated in accordance with ISO 11607-1:2019.
Sterilization Process has been validated accordance with ISO 11135:2014.
Result: The WiScope® Single-Use Digital Flexible Bronchoscope is sterile with a determination of lethal rate of the sterilization process to demonstrate achievement of the required SAL of 10^{-6} is in accordance to half cycle overkill approach.

Technological characteristics for WiScope® Single-Use Digital Flexible Bronchoscope have been tested for its functions as intended including verification of performance characteristics per ISO 8600 and performances characteristics relevant to functions as intended:

- Appearance
- Working length of the shaft,
- Minimum bending radius
- Working channel diameter
- Outer Shaft Diameter

- Depth of field
- Field of view
- Direction of view
- Rigid Distal Tip Temperature
- Tensile Force Testing
- Resolution
- Illumination
- Angulation range
- Working channel free from leakage
- Water proof
- Suction

Result: All tests were passed.

Simulated shipping distribution on aged devices test were conducted based on ASTM D4169-16.
Result: All tests were passed.

Software is developed according to ISO 13485 standard. It is verified and validated according to IEC 62304:2006. Cybersecurity Assessment is completed according to FDA Cybersecurity Guidance.

The results of Non-Clinical Performance testing demonstrate that the WiScope® Digital Bronchoscope System is considered safe and effective for its intended use.

10. Performance Data-Clinical

No clinical study is included in this submission.

11. Conclusion

It has been shown in this 510(k) submission that the differences between the proposed device and the predicate device do not raise different questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the relevant aspects of the predicate device in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.