April 13, 2022

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

Re: K212202
Trade/Device Name: WiScope® Digital Cystoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ
Dated: June 29, 2021
Received: March 10, 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 Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K212202

Device Name
WiScope® Digital Cystoscope System

Indications for Use *(Describe)*
WiScope® Digital Cystoscope System is intended to be used by physicians to access, visualize, and perform procedures in the bladder and lower ureter. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.

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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Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Sponsor

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Phone: (408) 797-7313
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

Feb 28th, 2022

4. Device Identification

Trade/Proprietary Name: WiScope® Digital Cystoscope System
Common Name: Cystoscope and Accessories, Flexible/rigid
Classification Name: Endoscope and Accessories
Product Code: FAJ
Regulation Number: 21 CFR 876.1500
Regulation Class: Class II
Review Panel: Gastroenterology/Urology

5. Predicate Devices

The proposed devices are substantially equivalent to the following predicate

Applicant	Device name	510(k) Number	Product code
Ambu Inc.	Ambu® aScope™ 4 Cysto	K193095	FAJ

6. Device Description

WiScope® Digital Cystoscope System is designed for physicians to access, visualize, and perform procedures in the bladder and lower ureter for diagnosis and treatment. This system includes a single-use digital cystoscope and an image system OTU-A.

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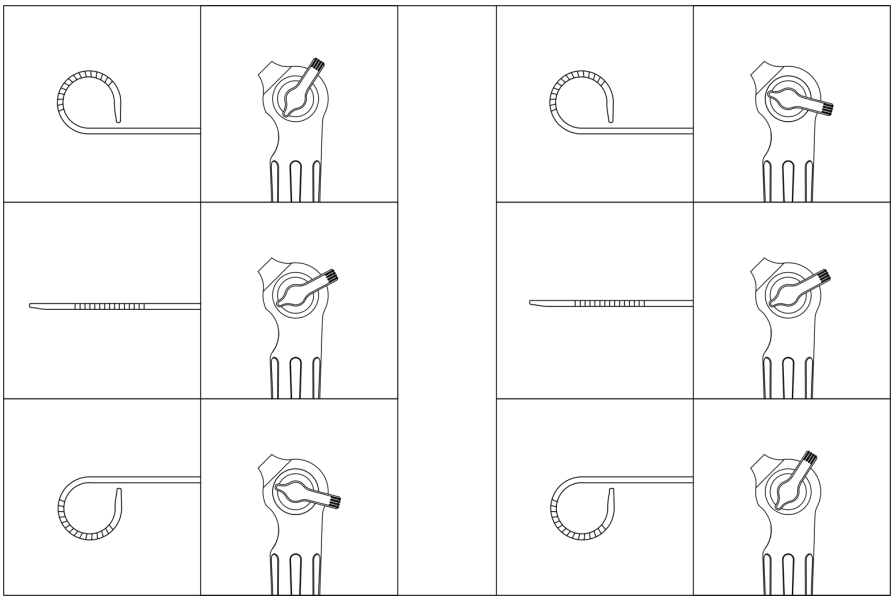
- The Image system OTU-A is currently marketed in the United States by OTU Medical Inc. under 510(k) # K181977.
- The single-use cystoscope is comprised of a control body with articulation controls and accessory access ports, and a flexible insertion tube with an on-tip camera module and LED lighting source.
- WiScope® Single-Use Digital Flexible Cystoscope has the following 4 models:
  OTU-C300S: Standard Deflection Model for OTU-C300 series
  OTU-C300R: Reverse Deflection Model for OTU-C300 series
  OTU-C310S: Standard Deflection Model for OTU-C310 series
  OTU-C310R: Reverse Deflection Model for OTU-C310 series
  Note:
  * Standard Deflection Models: Pushing the deflection lever forward articulates the distal tip "up" and pushing the lever back articulates the distal tip "down", as shown in Figure 1.
  * Reverse Deflection Models: Pushing the deflection lever forward articulates the distal tip "down" and pushing the lever back articulates the distal tip "up", as shown in Figure 1.



Standard Deflection Models **Reverse Deflection Models**

Figure 1. Illustration of standard deflection models vs. reverse deflection models.

The structure design and parts of the standard deflection models are the same as those of the reverse deflection model, i.e., OTU-C300S vs. OTU-C300R, OTU-C310S vs. OTU-C310R.

6.1 Specifications of the WiScope® Single-Use Digital Flexible Cystoscope

Item		OTU-C300S/ OTU-C300R	OTU-C310S/ OTU-C310R
	Size of CMOS image sensor	1mm×1mm	1mm×1mm
	Optical format of CMOS image	1/18"	1/18"

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Video Camera	sensor		
	Resolution of CMOS image sensor	400(H)×400(V) pixels	400(H)×400(V) pixels
	Optical Resolution	4lp/mm	4lp/mm
	Field of view	100°	100°
	Direction of view	Forward	Forward
	Depth of field	2 – 50 mm	2 – 50 mm
Light Source	Power rating and component specification of the LED light source	54 mW	54 mW
	Ratio of luminous energy transmitted to energy delivered	100 lm/W	100 lm/W
Shaft	Insertion tube type	Flexible	Flexible
	Distal tip diameter	10Fr	9Fr
	Maximum outer diameter of insertion portion	16Fr	15Fr
	Insertion tube outer diameter	15.3Fr	13.8Fr
	Working length of shaft	380 mm	380 mm
	Angulation range	210° Up / 210° Down	210° Up / 210° Down
Working Channel	Working channel diameter	6.6 Fr	6.6 Fr
	Flow rate	≥100 ml/min	≥100 ml/min
	Compatible fluids	Normal Saline	Normal Saline

Patient Contacting Materials:

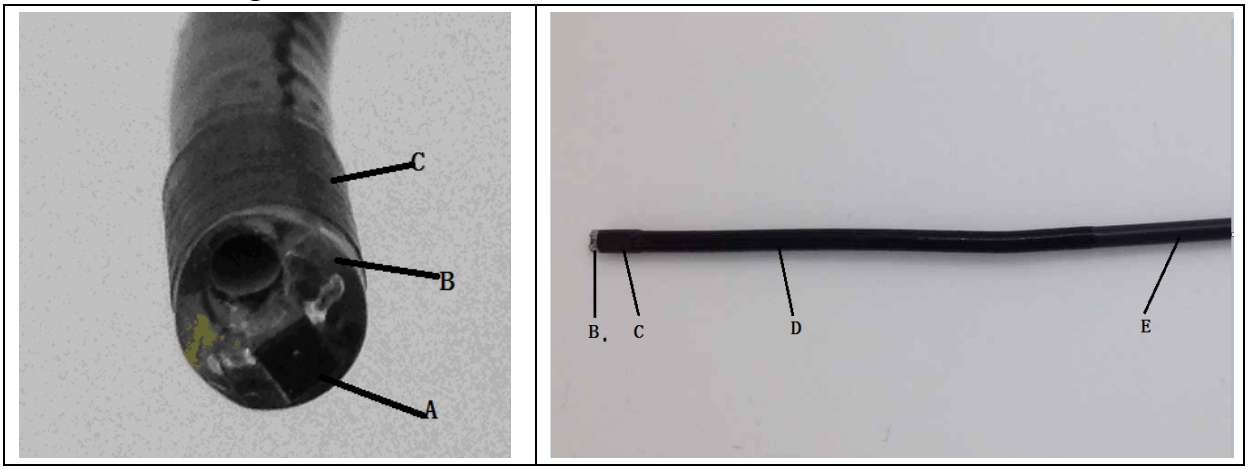

Figure 2. Photos of patient contacting materials

S/N	Components	Material
A	Lens of camera module	Glass
B	Distal tip	Polycarbonate (PC)
C	Rigid distal sleeve	Polycarbonate (PC)
D	Sheath of deflection section	Thermoplastic polyurethanes (TPU)
E	Shaft	PEBAX

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6.2 Non-patient contacting materials on shaft:

S/N	Components	Material
1	Camera system	LED, Sensor, PCB, electrical wires
2	Working channel connecter	Stainless steel 304
3	Working channel	PU
4	Deflection section	Stainless steel 304
5	Shaft	PEBAX, Stainless steel 304

7. Indication for Use Statement

The subject device: WiScope® Digital Cystoscope System is intended to be used by physicians to access, visualize, and perform procedures in the bladder and lower ureter. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.

The predicate device: Ambu® aScope™ 4 Cysto is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The Ambu® aScope™ 4 Cysto is intended to provide visualization via Ambu® displaying unit and can be used with endoscopic accessories. Ambu® aScope™ 4 Cysto is intended for use in a hospital environment or medical office environment. Ambu® aScope™ 4 Cysto is designed for use in adults.

WiScope® Digital Cystoscope System and the primary predicate device are similar in terms of indication for use. WiScope® Digital Cystoscope System is used in the bladder and lower ureter, while predicate device is used in the lower urinary tract. They are all for endoscopic examinations/diagnoses and therapeutic 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	Primary Predicate Device
Trade name	WiScope® Digital Cystoscope System	Ambu® aScope™ 4 Cysto
510(K) Submitter	OTU Medical Inc.	Ambu Inc.
510(K) Number	/	K193095
Classification Regulation	21CRF 876.1500	21CRF 876.1500
Classification and Code	Class II, FAJ	Class II, FAJ
Common name	Cystoscope and Accessories,	Cystoscope and Accessories,

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	Flexible/rigid	Flexible/rigid
Ureteroscope	Single-Use	Single-Use
Intended Use	WiScope® Digital Cystoscope System is intended to be used by physicians to access, visualize, and perform procedures in the bladder and lower ureter. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.	Ambu® aScope™ 4 Cysto is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The Ambu® aScope™ 4 Cysto is intended to provide visualization via Ambu® displaying unit and can be used with endoscopic accessories. Ambu® aScope™ 4 Cysto is intended for use in a hospital environment or medical office environment. Ambu® aScope™ 4 Cysto is designed for use in adults.
Digital video technology	CMOS	CMOS
Illumination	LED	LED
Field of View	100°	120°
Working Length (mm)	380	390
Insertion tube outer diameter	OTU-C300 series: 15.3Fr OTU-C310 series: 13.8Fr	16.2Fr
Working Channel Diameter (Fr)	6.6Fr	6.6Fr
Up/Down Deflection	UP: 210° DOWN: 210°	UP: 210° DOWN: 120°
Sterilization	EO SAL: 10^{-6}	EO SAL: 10^{-6}
Packaging	OTU-C300 series: packaged by paper-plastic bag. OTU-C310 series: packaged in a tray which is sealed by sterile barrier.	Cystoscope is packaged by paper-plastic bag.
Label and Labeling	Meet FDA's Requirements	Meet FDA's Requirements
Cytotoxicity	Comply with ISO 10993-5, no cytotoxicity effect	Comply with ISO 10993-5, no cytotoxicity effect
Irritation	Comply with ISO 10993-10, not an irritant	Comply with ISO 10993-10, not an irritant
Sensitization	Comply with ISO 10993-10, not a	Comply with ISO 10993-10, not

	sensitizer.	a sensitizer.

WiScope® Single-Use Digital Flexible Cystoscope has two series, OTU-C300 series and OTU-C310 series.

The differences between WiScope® Single-Use Digital Flexible Cystoscope OTU-C300 series and WiScope® Single-Use Digital Flexible Cystoscope OTU-C310 series have been described in 012_Section 10 Device Description in this 510K submission.

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 guidances.

ITEM	Proposed Device	Primary Predicate Device
Trade name	WiScope® Digital Cystoscope System	Ambu® aScope™ 4 Cysto
Safety Testing	*AAMI / ANSI ES60601-1:2012 *AAMI / ANSI / IEC 60601-1-2:2014 *IEC 60601-2-18:2009 *IEC IEC62471:2006 *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 *ASTM F88/F88M-15 *ISO 8600-1-2015 *ISO 8600-3-2019 *ISO 8600-4-2014 *ISO 8600-6-2005 *ASTM D4169-16	*IEC 60601-2-18:2009 *ISO 10993-5:2009 *ISO 10993-10:2010 *ISO 11135:2014 *ISO 8600-1-2015 *ISO 8600-3-2019 *ISO 8600-4-2014

WiScope® Digital Cystoscope 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.

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All evaluation acceptance criteria were met.

The biocompatibility evaluation for WiScope® Single-Use Digital Flexible Cystoscope 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 test is conducted based on ASTM F1980:
• Performance test
• Sterile Packaging Integrity
Result: All tests were passed.

Sterile barrier systems 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 Cystoscope 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 as described in Section 14 Sterilization and Shelf Life.

Technological characteristics have been tested for its functions as intended including verification of performance characteristics per ISO8600, ISO 12233 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
- Waterproof
- Flow rate of water

Result: All tests were passed.

Noise and dynamic range test were conducted based on ISO 15739.
Result: All evaluation acceptance criteria were met.

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

Photobiological safety test were conducted based on IEC 62471:2006.
Result: All tests were passed.

The results of Non-Clinical Performance testing demonstrate that the WiScope® Digital Cystoscope 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 any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards demonstrate that the proposed are 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.

Therefore, the proposed devices are determined to be substantially equivalent to the referenced predicate device.