July 22, 2021

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

Re: K210579
Trade/Device Name: WiScope OM Endoscope System,
WiScope Single-Use Digital Flexible Ureteroscope.
Choledochoscope, WiScope Image System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBN, FGB
Dated: June 15, 2021
Received: June 23, 2021

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
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant 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)*
K210579

Device Name
WiScope® OM Endoscope System

Indications for Use *(Describe)*
WiScope® OM Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney.
WiScope® OM Endoscope System is also intended to be used by physicians through percutaneous insertion to access, visualize, and perform procedures in the pancreaticobiliary system including the hepatic ducts and the common bile duct. 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.

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

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

1. Submission Sponsor
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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

Feb. 1th, 2021

4. Device Identification

Trade/Proprietary Name: WiScope® OM Endoscope System
Common Name/Classification Name: Endoscope and Accessories
Product Code: FBN, FGB
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 devices:

Applicant	Device name	510(k) Number	Product code
OTU Medical Inc.	WiScope™ Digital Endoscope System	K181977	FGB
ACMI Corporation	ACMI® DUR-Digital Ureteroscope and Choledochoscope System (DUR®-D)	K060269	FBN, FGB

6. Device Description
WiScope® OM Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney, and the pancreaticobiliary system including the hepatic ducts and the common bile duct. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.

This system includes a single-use digital ureteroscope/choledochoscope and an image system.

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WiScope® Single-Use Digital Flexible Ureteroscope/Choledochoscope is a modified version of the currently marketed WiScope Single-Use Digital Flexible Ureteroscope device that widen its application area from urinary system to bile ducts. Other than that, nothing has changed.
The image system stays the same.

7. Indication For Use Statement

WiScope® OM Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney.

WiScope® OM Endoscope System is also intended to be used by physicians through percutaneous insertion to access, visualize, and perform procedures in the pancreaticobiliary system including the hepatic ducts and the common bile duct.

The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.

8. Comparison of Technological Characteristics

A direct comparison of key characteristics demonstrates that the WiScope®OM Endoscope System is substantially equivalent to the predicate devices in terms of intended use, technological characteristics, and performance characteristics. The WiScope®OM Endoscope System is as safe and effective as the predicate devices.

ITEM	Proposed Device	Reference device	Predicate Device
Trade name	WiScope®OM Endoscope System	WiScope™ Digital Endoscope System	ACMI® DUR-Digital Ureteroscope and Choledochoscope System (DUR®-D)
510(K) Submitter	OTU Medical Inc.	OTU Medical Inc.	ACMI Corporation
510(K) Number	/	K181977	K060269
Classification Regulation	21CRF 876.1500	21CRF 876.1500	21CRF 876.1500
Classification and Code	Class II, FGB，FBN	Class II, FGB	Class II, FGB，FBN
Common name	Choledochoscope and Accessories, Flexible/rigid	Ureteroscope and Accessories, Flexible/rigid	Choledochoscope and Accessories, Flexible/rigid
Ureteroscope	Single-Use	Single-Use	Reuse
Intended Use	WiScope® OM Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney.	WiScope™ Digital Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary	The ACMI instrument system (which includes the DUR-Digital Invisio Flexible Ureteroscope, Choledochoscope, and IDC Invisio Digital

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	WiScope® OM Endoscope System is also intended to be used by physicians through percutaneous insertion to access, visualize, and perform procedures in the pancreaticobiliary system including the hepatic ducts and the common bile duct. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.	tract and the kidney. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.	Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and using additional accessories, can be used to perform various diagnostic and therapeutic procedures. The DUR-D System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.
Digital video technology	CMOS	CMOS	CMOS
Illumination	LED	LED	LED
Field of View (Diagonal)	100°	100°	80°
Working Length (mm)	670	670	650
Outer Shaft Diameter	8.6Fr	8.6Fr	9.3Fr
Working Channel Diameter (Fr)	3.6Fr	3.6Fr	3.6Fr
Up/Down Deflection	UP: 275° DOWN: 275°	UP: 275° DOWN: 275°	UP: 250° DOWN: 250°
Direction of View	0°	0°	9°
Brightness Control	Yes	Yes	Yes
White	Yes	Yes	No

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Balance			
Output Formats	USB/AV/HDMI	USB/AV/HDMI	USB/AV
Image/Video Capture	No	No	Yes
Camera Head Configurable	Yes	Yes	Yes
Sterilization	EO SAL: 10^{-6}	EO SAL: 10^{-6}	EO； SAL: 10^{-6}
Packaging	Ureteroscope/Choledochoscope is packaged in a tray which is sealed by sterile barrier.	Ureteroscope is packaged in a tray which is sealed by sterile barrier.	Ureteroscope is packaged in a storage container.
Label and Labeling	Meet FDA's Requirements	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 58953-6:2010 *ASTM F88/F88M-15 *ISO 8600-1-2015 *ISO 8600-3-2019 *ISO 8600-4-2014 *ISO 8600-6-2005	*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 11607-1:2006 *ASTM F1980-16 *ISO 11737-2:2009 *ASTM D3078-2013 *ASTM F1929-15 *DIN 58953-6:2010 *ASTM F88/F88M-15 *ISO 8600-1-2015 *ISO 8600-3-1997 *ISO 8600-4-2014 *ISO 8600-6-2005	*IEC 60601:1995 *IEC 60601-1-2:2004 *IEC 60601-2-18:2000 *UL 60601-1:2003 *CSA C22.2.125:1999
Cytotoxicity	Comply with ISO 10993-5, no cytotoxicity effect	Comply with ISO 10993-5, no cytotoxicity effect	Comply with ISO 10993-5
Irritation	Comply with ISO 10993-10, not an irritant	Comply with ISO 10993-10, not an irritant	Comply with ISO 10993-5
Sensitization	Comply with ISO 10993-10, not a	Comply with ISO 10993-10, not a	Comply with ISO 10993-10

	sensitizer.	sensitizer.	

Conclusion:

Usability Engineering was performed in accordance with IEC 62366 and stay the same as previous 510k submission.

Biocompatibility test was conducted in accordance with ISO 10993-5, ISO 10993-10, ISO 10993-11and the same as previous 510k submission.

The proposed devices share the same indications for use, device operation, overall technical and functional capabilities, meets the same standards and requirements and therefore are substantially equivalent to the predicate devices.

9. Non-Clinical Test Conclusion

Refer to the document of WiScope™ Digital Endoscope System which has been marketed in the United States by OTU Medical Inc. under 510(k) # K181977. There is no change on product design, materials and packaging. The no-clinical performance test stays the same as K181977.

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

It has been shown in this 510(k) submission that the difference between the proposed device and the predicate devices 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 devices 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 devices.