September 29, 2023

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

Re: K231702
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: September 1, 2023
Received: September 1, 2023

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 (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.

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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
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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)*

K231702

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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3. Date Prepared

September 28, 2023

4. Device Identification

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

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 Cystoscope System	K212202	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.

WiScope®Digital Cystoscope System has the same intended use to the predicate device. Both devices use the same CMOS image sensor technology, i.e., an CMOS image sensor at the scope tip, a back-end image/video processing system, and a cable connecting the CMOS sensor to the processing system. In addition, they have same mechanical functions, e.g., a handle with a

deflection control and a two-way deflectable insertion tube.

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

Detail device description please refer to Device Description in this submission.

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: WiScope® Digital Cystoscope System 510(k) # K212202 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.

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 single-use cystoscope: OTU-C300S; OTU-C300R OTU-C310S; OTU-C310R	WiScope® Digital Cystoscope System single-use cystoscope: OTU-C300S; OTU-C300R OTU-C310S; OTU-C310R
	Note: The WiScope® single-use cystoscope is currently marketed in the United States by OTU Medical Inc. under 510(k) # K212202.	
510(K)Submitter	OTU Medical Inc.	OTU Medical Inc.
510(K)Number	/	K212202
Classification Regulation	21 CFR 876.1500	21 CFR 876.1500
Classification and Code	Class II, FAJ	Class II, FAJ
Digital video technology	CMOS	CMOS
Illumination	LED	LED
Common name	Cystoscope and Accessories, Flexible/rigid	Cystoscope and Accessories, Flexible/rigid

OTU Medical Inc.
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Item	OTU-C300S/ OTU-C300R	OTU-C310S/ OTU-C310R
Field of view	100°	100°
Direction of view	Forward	Forward
Depth of Field	2-50mm	2-50mm
Distal tip diameter	10Fr	9Fr
Insertion tube outer diameter	15.3Fr	13.8Fr
Working length of shaft	380mm	380mm
Angulation range	210° Up / 210°Down	210° Up / 210°Down
Working channel diameter	6.6 Fr	6.6 Fr
Compatible fluids	Normal saline	Normal saline
Sterilization	EO SAL: 10^{-6}	EO SAL: 10^{-6}
Packaging	Packaged by paper-plastic bag	OTU-C300 series: packaged by paperplastic bag. OTU-C310 series: packaged in a tray which is sealed by sterile barrier.

The proposed device shares the same indications for use, same device operation, and overall technical and functional capabilities as the predicate device. The subject image system differs from the predicate in regard to the packaging of the WiScope® Single-Use Digital Flexible Cystoscope, shelf life, and camera module parameters. These differences do not raise different questions of safety and effectiveness as compared to the predicate, and can be evaluated through performance testing.

9. Description of Non-clinical Testing

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.

The biocompatibility evaluation for WiScope® Single-Use Digital Flexible Cystoscope was conducted in accordance with ISO 10993-1.

Sterilization Process for WiScope® Single-Use Digital Flexible Cystoscope has been validated accordance with ISO 11135:2014.

EO/ECH residual test for WiScope® Single-Use Digital Flexible Cystoscope was performed according to ISO 10993-7:2008.

Shelf life test for WiScope® Single-Use Digital Flexible Cystoscope is conducted based on ASTM F1980; Sterile barrier systems for WiScope® Single-Use Digital Flexible Cystoscope were evaluated in accordance with ISO 11607-1:2019.

Packaging Integrity Testing based on ISO 11607-1 and ASTM F1980-16

Photobiological safety testing based on IEC 62471:2006 and stay the same as K212202.

Electrical safety of the system was evaluated in accordance with IEC 60601-1 and IEC 60601-2-18. Electromagnetic compatibility was evaluated in accordance with IEC 60601-1-2.

Optical and Color Performance Testing:

- Resolution
- Depth of field
- Distortion
- Signal to noise ratio
- Dynamic Range
- Image/Brightness Uniformity
- Color performance

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 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 device is determined to be substantially equivalent to the predicate device.