August 14, 2018

OTU Medical Inc.
% David Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, NJ 07041

Re: K181977
Trade/Device Name: WiScope™ Digital Endoscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB
Dated: July 20, 2018
Received: July 24, 2018

Dear David Yungvirt:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K181977

Device Name
WiScope™ Digital Endoscope System

Indications for Use *(Describe)*
WiScope™ Digital Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary 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.

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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2231A Fortune Drive, San Jose, CA 95131

# Section 5
# 510(k) Summary

[As required by 21 CFR 807.92]

## 1. Submission Sponsor

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## 3. Date Prepared

May 14, 2018

## 4. Device Identification

Trade/Proprietary Name: WiScope™ Digital Endoscope System
Common Name/Classification Name: Ureteroscope and Accessories, Flexible/rigid
Product Code: FGB
Regulation Number: 21 CFR 876.1500 Endoscope and Accessories
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 |
|---|---|---|---|
| Zhuhai Pusen Medical Technology Co., Ltd. | Medical Video Endoscope System | K171076 | FGB |

## 6. Device Description

WiScope™ Digital Endoscope System is designed for physicians to access, visualize, and perform

procedures in the urinary tract for diagnosis and treatment. This system includes a single-use digital ureteroscope and an image system.

The single-use ureteroscope 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. The image system processes the images from the ureteroscope and outputs video signals to a display.

## 7. Indication For Use Statement

WiScope™ Digital Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary 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.

## 8. Comparison of Technological Characteristics

The following table compares the proposed device with the predicate device 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 | Remark |
|---|---|---|---|
| Trade name | WiScope™ Digital Endoscope System | Medical Video Endoscope System | |
| 510(K) Submitter | OTU Medical Inc. | Zhuhai Pusen Medical Technology Co., Ltd. | |
| 510(K) Number | | K171076 | |
| Classification Regulation | 21CRF 876.1500 | 21CRF 876.1500 | SE |
| Classification and Code | Class II, FGB | Class II, FGB | SE |
| Common name | Ureteroscope and Accessories, Flexible/rigid | Ureteroscope and Accessories, Flexible/rigid | SE |
| Ureteroscope | Single-Use | Single-Use | SE |
| Image System | Not including OS, monitor, and battery | Including a touch PC and battery | Analysis 1 |

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| | | | |
|---|---|---|---|
| Intended Use | WiScope™ Digital Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary 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. | This instrument has been designed to be used with endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney. | Note 1 |
| Digital video technology | CMOS | CMOS | Note 2 |
| Illumination | LED | Optical fiber | Analysis 2 |
| Field of View (Diagonal) | 100° | 120° | Note 3 |
| Outer Shaft Diameter | 8.6Fr | 9.0Fr | Note 4 |
| Working Length (mm) | 670 | 630 | Note 4 |
| Working Channel Diameter (Fr) | 3.6Fr | 3.6Fr | SE |
| Up/Down Deflection | UP: 275°<br>DOWN: 275° | UP: 270°<br>DOWN: 270° | SE |
| Direction of View | 0° | 0° | SE |
| Brightness Control | Yes | Yes | SE |
| White Balance | Yes | Yes | SE |
| Output Formats | USB/AV/HDMI | USB/AV/HDMI | SE |
| Image/Video Capture | No | Yes | Analysis 3 |
| Camera Head Configurable | Yes | Yes | SE |
| Sterilization | EO<br>SAL: 10-6 | EO<br>SAL: 10-6 | SE |
| Packaging | Ureteroscope is packaged in a tray which is sealed by sterile barrier | Ureteroscope is packaged in a tray which is sealed by sterile barrier | SE |
| Label and Labeling | Meet FDA's Requirements | Meet FDA's Requirements | SE |

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| | | | |
|---|---|---|---|
| Safety Testing | *AAMI / ANSI ES60601-1:2012<br>*AAMI / ANSI / IEC 60601-1-2:2014<br>*IEC 60601-2-18:2009<br>*AAMI / ANSI / ISO 10993-5:2009<br>*ISO 10993-10:2010<br>*ISO 11135:2014<br>*ISO 10993-7:2008<br>*ISO 11607-1:2006<br>*ASTM F1980-16<br>*ISO 11737-2:2009<br>*ASTM D3078-2013<br>*ASTM F1929-15<br>*DIN 58953-6:2010<br>*ASTM F88/F88M-15<br>*ISO 8600-1-2015<br>*ISO 8600-3-1997<br>*ISO 08600-4-2014<br>*ISO 8600-6-2005 | *AAMI / ANSI ES60601-1:2012<br>*IEC 60601-1-2:2007<br>*IEC 60601-2-18:2009<br>*ISO 10993-5:2009<br>*ISO 10993-10:2010<br>*ISO 11135:2014<br>*ISO 11607:2006<br>*ISO 8600 | Performed more testing than the predicate to show safety |

Note 1:
WiScope™ Digital Endoscope System and the predicate device are similar in terms of indication for use. They are all used in the urinary tract and the kidney. They are both for endoscopic examinations/diagnoses and therapeutic procedures with endoscopic accessories.

Note 2:
WiScope™ Digital Endoscope System and the predicate device use the similar CMOS image sensor technology, i.e., an CMOS image sensor at the ureteroscope tip, a back-end image/video processing system, and a cable connecting the CMOS sensor to the processing system.

Note 3:
WiScope™ ureteroscope has a field of view (FOV) of 100°, and the predicate device claimed a field of view of 120°. However, a comparison study between the proposed and the predicate device by physicians demonstrates that the optical parameter is similar and it does not affect safety and effectiveness.

Note 4:
WiScope™ ureteroscope's outer shaft diameter (8.6Fr) is smaller than the predicate device's 9.0Fr. The shaft working length (670mm) is longer than the predicate device's 630mm.

The longer working length allows for better operating flexibility of the proposed device than the predicate.

The smaller outer shaft diameter is even better, which allows for better performance of the proposed device than the predicate, because it facilitates passage of the ureteroscope up the ureter and into the kidney.

Analysis1:
OTU's image system does not include the Operating System (OS), the monitor, and the battery, while the predicate does include a PC with a touch screen, and a battery. OTU's image system is connected to a single-use ureteroscope and an existing monitor in the operating room via a standard video connector, i.e., CVBS or HDMI, and is AC powered up for a clinical procedure. As compared to the predicate device, using the external monitor offers better flexibility to use the proposed device. In addition, the proposed image system has passed all safety and EMC testing. Therefore, we consider both devices are substantially equivalent.

Analysis 2:
The proposed device has an LED lighting source directly installed at the distal-end, while the predicate device has the optical fibers at the distal-end and the LED source at the proximal-end. The LED lighting sources ensure high image quality of the ureteroscope. In addition, the proposed device has passed all distal tip temperature tests, and it meets the requirements of IEC 60601-1. Thus we consider that both devices are substantially equivalent.

Analysis 3:
The proposed device doesn't have integrated image/video capture function in the system. However, this feature can be implemented by using legally marketed video recorder or software. The implementations also comply with cybersecurity requirements, and more detailed analysis is described in the report of Cybersecurity Risk Assessment. Therefore, both devices are the same in this aspect.

Table 5B – Biocompatibility Comparison

| ITEM | Proposed Device | Predicate Device | Remark |
|---|---|---|---|
| Cytotoxicity | Comply with ISO 10993-5, no cytotoxicity effect | Comply with ISO 10993-5 | SE |
| Irritation | Comply with ISO 10993-10, not an irritant | Comply with ISO 10993-10 | SE |
| Sensitization | Comply with ISO 10993-10, not a sensitizer. | | SE |

**Conclusion:**
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 device.

**9. Non-Clinical Test Conclusion**

The WiScope™ Digital Endoscope System has been verified for its safety and effectivity based on the following performance data.

Electrical safety of the system was evaluated in accordance with IEC 60601-1:2012, and AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012,C1:2009/(R)2012 And A2:2010/(R)2012 and IEC 60601-2-18:2009. Electromagnetic compatibility was evaluated in accordance with IEC 60601-1-2:2014. All evaluation acceptance criteria were met.

The biocompatibility evaluation for the Medical Video Endoscopy system was conducted in accordance with the Guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"" June 16, 2016, 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.
Biocompatibility of the patient contacting materials were evaluated safe in accordance with ISO 10993-1:2009/(R)2013.

Sterile barrier systems were evaluated in accordance with ISO 11607-1:2006.
Sterilization Process has been validated accordance with ISO 11135:2014.

Technological characteristics has been tested for its functions as intended including verification of performance characteristics per ISO8600 (Appearance, The minimum bending radius, The Working length of shaft, Perimeter, Depth of field, Field of view, Direction of view) and performances characteristics relevant to functions as intended(Resolution, Rigid distal tip temperature, Illumination, Articulation, Working channel freedom from leakage, Waterproof, Flow rate of water, Function keys, OLED display).

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

**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 devices 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.