August 26, 2022

Shanghai AnQing Medical Instrument Co., Ltd.
Shuwen Fan
RA Manager
3 & 4 Floor, No.2 Building, 366 Huiqing Rd,
East Zhangjiang High-Tech Park
Shanghai, 201201
China

Re: K220159
Trade/Device Name: Flexible Ureterorenoscope
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB
Dated: July 27, 2022
Received: July 27, 2022

Dear Shuwen Fan:

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,

Reginald K. Avery, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220159

Device Name
Flexible Ureterorenoscope

Indications for Use *(Describe)*
The Flexible Ureterorenoscope is intended to be used to visualize organs, cavities, and canals in the urinary tract (urethra, bladder, ureter, calyces, and renal papillae) via transurethral access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

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

Date Prepared:	Aug. 18th, 2022
Manufacturer:	Shanghai AnQing Medical Instrument Co., Ltd. 3 & 4 Floor, No.2 Building, 366 Huiqing Rd, East Zhangjiang High-Tech Park, 201201 Shanghai, China
Contact Person:	Shuwen Fan RA Manager Shanghai AnQing Medical Instrument Co., Ltd. Tel: +86-21-61117375 Fax: +86-21-61117374 ra_dept@anqing-sh.com

Identification of the Device:

Proprietary/Trade Name:	Flexible Ureterorenoscope
Model:	US31D-12-EU, US31D-12-US
Common or Usual Name:	Ureteroscope and accessories, flexible/rigid
Classification Name:	Endoscope and accessories
Regulatory Number:	21 CFR Part 876.1500
Product Code:	FGB
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Identification of the Legally Marketed Predicate Device:

Trade Name:	Ureterorenoscope System
Classification Name:	Endoscope and accessories
Regulatory Number:	21 CFR Part 876.1500
Product Code:	FGB
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Submitter/510(k) Holder:	Shanghai AnQing Medical Instrument Co., Ltd.
Clearance:	K201293 (cleared July 24, 2020)

This predicate has not been subject to a design-related recall.

Device Description:

The Flexible Ureterorenoscope (Model: US31D-12-EU, US31D-12-US) is an endoscope which is used with the Video Processor (Model: EOS-H-01) (FDA cleared

#K211169) produced by AnQing for providing endoscopic imaging of the ureter and the renal pelvis for the purpose of diagnosis and treatment. The 2 proposed models are identical except the deflection versions, which is opposite from each other (EU version or US version).

The Flexible Ureterorenoscope is a single-use endoscope, which consists of a Handle, an Insertion Section, and an Endoscope Connector. The handle includes a deflection lever, a lever lock, a push button for picture taking/video recording and a Luer port for insertion of accessory devices and irrigation to the working channel. The insertion section contains one working channel and wiring to transmit the image signals to the Video Processor. The distal bending section of the insertion section is controlled by the user via the deflection lever on the handle. The distal end of the insertion section contains a CMOS sensor for capturing image and transmitting it to the Video Processor, LEDs for illumination, and the distal opening of the working channel. The endoscope connector connects the endoscope handle to the video processor, which provides power and processes video signals from the endoscope.

Mechanism of action:

The light emitted by the LED cold light source at the distal tip of the disposable Flexible Ureterorenoscope is irradiated into the body cavity, and the light reflected from the cavity enters the optical system and is captured by the CMOS image sensor. The CMOS acquisition image is controlled by the CMOS drive circuit, and the RGB video signal is output to the Video Processor via the VI circuit. The Video Processor receives video signals from the endoscope, processes the video signals, and outputs the processed video signal to the attached monitor. The video processor also controls the brightness of the LEDs on the endoscope.

Flexible Ureterorenoscope has the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Flexible insertion cord
- Camera and LED light source at the distal tip
- Sterilized by Ethylene Oxide
- For single use

Indications for Use:

The Flexible Ureterorenoscope is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

Comparison with Predicate Device:

The Flexible Ureterorenoscope and its predicate device, the Shanghai AnQing Medical Ureterorenoscope System (K201293), have the same intended use, sterilization Methods and similar physical characteristics, optical characteristics.

Substantial Equivalence:

The Flexible Ureterorenoscope employs the same fundamental scientific technology as its predicate devices, as below table:

	Subject Device	**Predicate Device, K201293**	**Comparison**
Indications For Use			
Indications For Use:	The Flexible Ureterorenoscope is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.	The Ureterorenoscope System consists of a sterile single-use Flexible Ureteroscope to be introduced within the urinary tract and video processor for clinical image processing. The device is indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures.	Same. See Note2.
	Physical Characteristics		
Type of Scope	Flexible	Flexible	Same
Distal end outer diameter	≤3.2mm (9.6Fr)	≤3.1mm (9.3 Fr)	Similar
Insertion Section length	670mm	650mm	Similar

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	Subject Device	Predicate Device, K201293	Comparison
Deflection	≥275°up/275°down	≥275°up/275°down	Same
	Optical Characteristics		
Type of Imager	CMOS	CMOS	Same
Direction of View	forward	forward	Same
Field of View	110°	110°	Same
Depth of Field	3mm~100mm	3mm~100mm	Same
Light Source	Internal LED	Internal LED	Same
	Patient Contacting Materials		
General material type of main patient-contact part	Pebax, polyamide, Stainless Steel, Epoxy glue, glass, Polycarbonate, PTFE, PET	Pebax, PTFE, LCP, TPU, Fluoro elastomers, Epoxy glue, glass	Different See Note1.
	Sterilization Methods		
Number of Users	Single-Use	Single-Use	Same
Sterilization	EO Sterilized, SAL 10^{-6}	EO Sterilized, SAL 10^{-6}	Same
	Technological Characteristics		
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital	Same
Energy source	Electricity	Electricity	Same

Note：

1. The subject and predicate devices have the same fundamental technology, direction of view, depth of field, light source, type of imager, number of uses and sterilization method. The subject ureterorenoscope differs from the predicate in insertion section length, distal end outer diameter and patient-contacting materials. These differences do not raise different questions of safety and effectiveness as compared to the predicate, and can be evaluated through performance testing.

	Subject Device	Predicate Device, K201293	Comparison
2. The indications for use statement for the subject ureterorenoscope is very similar to that of the predicate device. A slightly different wording is chosen and specific anatomical locations within the urinary tract are listed. The differences do not alter the intended use of the device nor do they raise different questions of safety and effectiveness of the device relative to the predicate.			

Summary of Testing:

Summary of Non-Clinical Tests:

Electrical Safety and Electromagnetic Compatibility Summary

The electrical safety and EMC data included in the submission is in compliance with the following FDA recognized standards:

- ANSI/AAMI ES: 60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012
- IEC 60601-2-18:2009
- IEC 60601-1-2:2014

Bench Testing Summary

Photobiological safety

The LEDs in submitted Ureterorenoscope were tested according to the following FDA recognized standards:

- IEC 62471:2006 Medical electrical equipment, Photobiological safety of lamps and lamp systems

Mechanical and Optical Performance

The Flexible Ureterorenoscope was designed to comply with applicable parts of ISO 8600. Optical measurements were performed according to applicable part of ISO 8600 standard.

Mechanical characteristics were tested and include leakage tightness, bending, deflection endurance, and tensile strength testing.

In addition, comparative testing related to image quality parameters including Color performance (color reproduction), optical performance (resolution, depth of field and image intensity uniformity, distortion), and dynamic range test was performed for submitted Flexible Ureterorenoscope and the predicate device to support substantial equivalence.

Biocompatibility Summary

The biocompatibility evaluation for the patient contacting components of the Flexible Ureterorenoscope was performed according to ISO 10993-1 and FDA Guidance. The

following tests were conducted based contact category of "Surface-Breached or compromised surface" with a contact duration of "Limited (< 24 hours):

- Cytotoxicity: ISO 10993-5:2009/(R) 2014
- Sensitization, Intracutaneous reactivity/irritation: ISO 10993-10:2010
- Material-mediated pyrogenicity: ISO 10993-11:2017
- Acute systemic toxicity: ISO 10993-11:2017

Sterilization and shelf life testing

The sterilization method has been validated to ISO 11135:2014, which has thereby determined the routine control and monitoring parameters.

EO/ECH residual test was performed according to ISO 10993-7:2008.

The shelf life (3 years) of the Flexible Ureterorenoscope is determined based on stability study which includes ageing test according to ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier.

Package Validation

Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and visual inspection (ASTM F1886), seal strength (F88/F88M-15), dye penetration (ASTM F1929-15), and bubble emission (ASTM D3078).

Transport and shipping testing as per ASTM D4169-16.

Summary of Clinical Tests:

The subject of this premarket submission did not require clinical studies to support substantial equivalence.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device, the Flexible Ureterorenoscope is substantially equivalent to the predicate device.