October 5, 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: K222737
Trade/Device Name: Flexible Ureterorenoscope
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB
Dated: September 9, 2022
Received: September 9, 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,

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

Indications for Use Statement

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)*

K222737

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date Prepared: Sep. 27th, 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
ra_dept@anqing-sh.com

Type of 510k Submission: Special

Identification of the Device:

Proprietary/Trade Name:	Flexible Ureterorenoscope
Model:	US31E-12-EU, US31E-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:

Predicate#	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220159	Flexible Ureterorenoscope (Model: US31D-12-EU; US31D-12-US)	FGB

The above predicates have not been subject to a design-related recall.

Identification of the Reference Device:

Reference#	Reference Trade Name	Product Code
K201293	Ureterorenoscope System	FGB

Device Description Summary:

The Flexible Ureterorenoscope (Model: US31E-12-EU; US31E-12-US) is intended to be used with the Video Processor (cleared in K211169). The Flexible Ureterorenoscope is inserted through the natural orifice urethra and when used with the compatible Video Processor and monitor, the endoscope system can be operated as intended and indicated. 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 working channel port for accessory devices and a Luer port for irrigation. 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. Same as the predicate, the subject device is also provided in 2 deflection versions (US/EU deflection), which is the only difference between the two proposed models.

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

The subject device is a simplified alternative to the predicate device by adopting the handle of the reference device. The handle design of the subject device is different from the predicate on the following:

1. Same as the reference device, the subject device has no video/photo pushbutton or deflection lever lock on the handle.

2. Same as the reference device, the subject device adopts a built-in Luer connector with a stopcock for irrigation and a built-in working channel port for insertion of flexible auxiliary instruments whereas the predicate supports a detachable T-Luer for both irrigation and insertion of flexible auxiliary instruments.

Intended 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.

Indications for use Comparison:
The subject device has same indication for use in comparison to the predicate device.

Technological Characteristics:
The subject device is a modification of the predicate device, US31D-12-EU/US, cleared via K220159 and also incorporates handle design features of the reference device, US31A-12 and US31B-12, cleared via K201293.
The subject and predicate device have the same fundamental technology, physical characteristics, optical characteristics, number of uses, and sterilization. A comparison between the proposed device and predicate device is included in the table below:

Comparison Table: Subject vs. Predicate Device

	Subject Device	**Predicate Device, K220159**
510(K) Submitter	Shanghai AnQing Medical Instrument Co., Ltd.	Same
Classification Regulation	21 CFR Part 876.1500	Same
Classification and Code	Class II, FGB	Same
	Physical Characteristics	
Type of Scope	Flexible	Same
Distal end outer diameter	≤3.2mm (9.6Fr)	Same as subject device
Working Channel Diameter	≥1.2 mm (3.6Fr)	Same
Insertion Section length	670mm	Same as subject device
Deflection	≥275°up/275°down	Same

	Subject Device	Predicate Device, K220159
	Optical Characteristics	
Type of Imager	CMOS	Same
Direction of View	forward	Same
Field of View	110°	Same
Depth of Field	3mm~100mm	Same
Light Source	Internal LED	Same
	Material/ Design Characteristics	
Photo/video push button	No.	Yes
Detachable T-Luer	No. The device adopts a built-in Luer connector with stopcock for irrigation and a built-in working channel port for insertion of flexible auxiliary instruments.	Yes
Deflection Lever Lock	No	Yes
	Sterilization Methods	
Number of Users	Single-Use	Same
Sterilization	EO Sterilized, SAL 10^{-6}	Same
	Technological Characteristics	
Environment of use	Healthcare facility/hospital	Same
Energy source	Electricity	Same

Non-Clinical Performance Data:

As part of demonstrating substantial equivalence to the predicate, a risk analysis was completed to identify the risks associated with the modification on the endoscope handle and secondary package dimensions. Verification testing were conducted to evaluate the modifications. The following tests associated with the device modifications were performed on the subject device according to methods and acceptance criteria outlined in the predicate. The subject device passed all the testing in accordance with internal requirements and applicable standards to support substantial equivalence of the subject device.

Mechanical Performance

Mechanical characteristics were tested and include tensile strength at joints/connections, coaxiality, deflection endurance, withstand of channel.

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 on contact category of "Surface – Breached or Compromised Surface" with a contact duration of "Limited (< 24 hours):

- Cytotoxicity per ISO 10993-5:2009/(R) 2014
- Irritation per ISO 10993-10:2010
- Sensitization per ISO 10993-10:2010
- Acute Systemic Toxicity per ISO 10993-11:2017
- Material-mediated pyrogenicity per ISO 10993-11:2017

Sterilization

The sterilization method has been validated to ISO 11135:2014 half-cycle method, which has thereby determined the routine control and monitoring parameters.
EO/ECH residual test was performed according to ISO 10993-7:2008.

Simulated Shipping distribution followed by sterile packaging integrity test

Package validation was conducted according to ISO 11607-1:2019 and ISO 11607- 2:2019, and

- Environmental conditioning ASTM D4169-16
- Transportation Simulation ASTM D4169-16
- Seal strength F88/88M-15
- Seal integrity ASTM F 1929-15

Substantial Equivalence:

The intended use, operating principles, technological characteristics and features are similar, if not identical, between that subject device and the predicate device, Flexible Ureterorenoscope (K220159). The minor difference between the subject and predicate device that does not raise new or different questions on safety and effectiveness are listed above in Technological Characteristics section.
As demonstrated by the comparisons, the differences do not raise different questions of safety and effectiveness because the intended use, operating principles, technological characteristics, and features are similar, if not identical. Both subject device and predicate device also comply with identical standards and safety testing, where applicable.
Substantial equivalence to the effectiveness of the subject device is supported by the comparison of the performance characteristics including, but not limited to the performance testing listed above.

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 (Model: US31E-12-EU; US31E-12-US) is substantially equivalent to the predicate device.