April 11, 2025

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: K243857
Trade/Device Name: Flexible Ureterorenoscope (US27F-12-EU; US27F-12-US)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: March 14, 2025
Received: March 14, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,
Gynecology, and Urology Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243857

Device Name

Flexible Ureterorenoscope (US27F-12-EU; US27F-12-US)

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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Contact Details

21 CFR 807.92(a)(1)

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Applicant Contact	Ms. Shuwen Fan
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Flexible Ureterorenoscope (US27F-12-EU; US27F-12-US)
Common Name	Endoscope and accessories
Classification Name	Ureteroscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FGB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220159	Flexible Ureterorenoscope	FGB

Device Description Summary

21 CFR 807.92(a)(4)

The Flexible Ureterorenoscope (Model: US27F-12-EU; US27F-12-US) is intended to be used with the Video Processor (cleared via 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 lever lock, a push button for picture taking/video recording, a Luer port for insertion of accessory devices and irrigation to the working channel and a LED for illumination. The insertion section contains one working channel, wiring to transmit the image signals to the Video Processor, and two optical fibers to transmit illumination from the handle to the distal tip. 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, optical fibers for transmitting illumination from the LED inside the Handle, 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 from the distal tip of the 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 LED on the endoscope.
Flexible Ureterorenoscope has the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Flexible insertion cord

- Camera at the distal tip
- LED in the handle and transmitted to the distal tip by optical fibers
- Sterilized by Ethylene Oxide
- For single use

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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 21 CFR 807.92(a)(5)

The indication for use of the subject device and the predicate device(s) are the same.

Technological Comparison 21 CFR 807.92(a)(6)

1. The subject and predicate devices have the same fundamental technology, insertion section length, deflection, direction of view, depth of field, type of imager, number of uses and sterilization method.
The subject device differs from the predicate in distal end outer diameter, field of view 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.

2. Both the subject device and predicate device provides LED illumination to the procedural site, which in the case of the predicate device is provided by the LEDs in the distal tip, whereas in the case of the subject device, the illumination is generated by the LED inside of the handle and transmitted to the distal tip via optical fibers. This difference does not raise different questions of safety and effectiveness as compared to the predicate, and can be evaluated through performance testing.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

1. 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 ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
• ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]
• IEC 60601-2-18 Edition 3.0 2009-08
• IEC/TR 60601-4-2 Edition 1.0 2016-05

2.Photobiological safety
The proposed device was tested according to the following FDA recognized standards:
• IEC 62471:2006 Medical electrical equipment, Photobiological safety of lamps and lamp systems

3. Mechanical and Optical Performance
The proposed device 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 direction of view, field of view, MTF/DOF, color performance, SNR/Dynamic Range, Distortion,and Image intensity uniformity was performed for proposed device and the predicate device to support substantial equivalence.

4. The biocompatibility evaluation for the patient contacting components of the proposed device was performed according to ISO 10993-1 and FDA Guidance. The following tests were conducted: Cytotoxicity, Sensitization, Irritation, Material-mediated pyrogenicity, Acute systemic toxicity.

5. 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 of the proposed device is determined based on stability study which includes aging test according to ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier.

6. Package Validation

ackage validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and ASTM F88/F88M-21, ASTM F1929-15 Transport and shipping testing as per ASTM D4169-22.

Clinical Testing: Not Applicable.

The conclusions drawn from the nonclinical tests demonstrate that the subject device, the Flexible Ureterorenoscope is as safe, as effective, and performs as well as the legally marketed device identified above.