July 24, 2020

Shanghai AnQing Medical Instrument Co., Ltd.
Shuwen FAN, RA Manager
3rd & 4th Floor, No.2 Building
366 Huiqing Road
Zhangjiang High-Tech Park
Shanghai, 201201
CHINA

Re: K201293
Trade/Device Name: Ureterorenoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: June 23, 2020
Received: June 25, 2020

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,

Martha Betz
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

Section 4 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201293

Device Name
Ureterorenoscope System

Indications for Use *(Describe)*
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 track and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

Section 5 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of AnQing's knowledge.

Submitter:	Shanghai AnQing Medical Instrument Co., Ltd 3 &4 Floor, No.2 Building, 366 Huiqing Rd , East Zhangjiang High-Tech Park, Shanghai, China
Contact:	Shuwen Fan Regulatory Affairs Manager Email: shuwenfan@anqing-sh.com Tel: 00862161117375 Fax: 00862161117374
Date of Preparation:	July 23, 2020
Type of 510(k) Submission:	Special 510(k) K201293
Device Identification:	Trade Name: Ureterorenoscope System Common Name: Ureteroscope and accessories, flexible/rigid Classification Name: Endoscope and accessories (21 CFR Part 876.1500)
Regulatory Class:	II
Product Code:	FGB
Predicate Device(s):	Shanghai AnQing Medical Ureterorenoscope System (K180367) This predicate has not been subject to a design-related recall.
Device Description:	The Ureterorenoscope System consists of a sterile single-use Flexible Ureteroscope to be introduced within the urinary tract and a non-sterile repeat use Video Processor for clinical image processing.

<table>
<tr><td>Intended Use:</td><td>The Ureterorenoscope System is intended for visualization purposes during urological diagnostic and therapeutic procedures.</td></tr>
<tr><td>Indications For Use:</td><td>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.</td></tr>
<tr><td>Technological Characteristics:</td><td>Comparison Table: Subject vs. Predicate Device
<table>
<tr><td></td><td>Subject Device</td><td>Predicate Device, K180367</td></tr>
<tr><td></td><td colspan="2">Physical Characteristics</td></tr>
<tr><td>Type of Scope</td><td>Flexible</td><td>Same as the Subject device</td></tr>
<tr><td>Distal end outer diameter</td><td>9.3 Fr</td><td>Same as the Subject device</td></tr>
<tr><td>Insertion Section length</td><td>650mm</td><td>650mm</td></tr>
<tr><td>Deflection</td><td>275 °up/275 °down</td><td>Same as the Subject device</td></tr>
<tr><td></td><td colspan="2">Optical Characteristics</td></tr>
<tr><td>Type of Imager</td><td>CMOS</td><td>Same as the Subject device</td></tr>
<tr><td>Direction of View</td><td>Forward Viewing</td><td>Same as the Subject device</td></tr>
<tr><td>Field of View</td><td>110 °±5%</td><td>Same as the Subject device</td></tr>
<tr><td>Light Source</td><td>Internal LED</td><td>Same as the Subject device</td></tr>
<tr><td colspan="3">Patient Contacting Materials</td></tr>
<tr><td>Direct</td><td>LCP, TPU, Fluoro elastomers, Expoxy glue</td><td>LCP, TPU</td></tr>
<tr><td>Indirect</td><td>Pebax, PTFE</td><td>Pebax</td></tr>
<tr><td></td><td colspan="2">Sterilization Methods</td></tr>
<tr><td>Number of Users</td><td>Endoscope: Single-Use
Video Processor: reusable</td><td>Same as the Subject device</td></tr>
<tr><td>Endoscope Primary Package</td><td>Material: PETG & Tyvek

Size: 1063*131*43 mm</td><td>Material: PETG & Tyvek

Size: 495*270*43 mm</td></tr>
<tr><td>Endoscope Sterilization</td><td>EO Sterilized, SAL 10^{-6}</td><td>Same as the Subject device</td></tr>
</table></td></tr>
</table>

	The subject and predicate devices have the same fundamental technology, insertion section length, field and direction of view, light source, image display, number of uses and sterilization. The subject ureteroscope differs from the predicate in patient-contacting materials, and size of the primary package. These differences do not raise different questions of safety and effectiveness as compared to the predicate. The indication for use of the subject and the predicate device are identical.
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 endoscope material changes and package size change. 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 device (K180367). The subject device passed all the testing in accordance with internal requirements and applicable standards to support substantial equivalence of the subject device. **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 –Mucosal Membrane" 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 **Sterilization** The sterilization method has been validated to ISO11135:2014, which has thereby determined the routine control and monitoring parameters. • Bioburden per ISO 11737-1:2018 • EO and ECH residuals per ISO 10993-7:2008 **Accelerated Aging followed by sterile packaging integrity test** **Simulated Shipping distribution followed by sterile packaging integrity test** **Mechanical Performance test** • Water Resistance • Bending Reliability • Angulation/deflection test

Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish the substantial equivalence of the modifications.
Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject device, the Ureterorenoscope System is substantially equivalent to the predicate devices.