July 3, 2018

Shanghai AnQing Medical Instrument CO., Ltd.
Lina Fei
Quality Manager
150 Cailun Road, Zhangjiang High-Tech Park
Shanghai, 201210
China

Re: K180367
Trade/Device Name: Ureterorenoscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB
Dated: May 18, 2018
Received: May 29, 2018

Dear Lina Fei:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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)*
K180367

Device Name
Ureterorenoscope System

Indications for Use *(Describe)*
The Ureterorenoscope System consists of a sterile single-use disposable 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.

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

I Submitter

Device submitter: Shanghai AnQing Medical Instrument CO., Ltd.
Room 202, 2nd Floor, No.7 Building & Room 202, 2nd Floor No.4 Building,
150 Cailun Road, Zhangjiang High-Tech Park, 201210, Shanghai, China

Contact: Lina FEI, Quality Manager
Phone: +86 137 7425 3128
Fax: +86 21 5019 1132 – 8004
Email: Lina@anqing-sh.com

II Device

Trade name of Device: Ureterorenoscope System
Common name: Ureteroscope and Accessories, Flexible/Rigid
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscopes and Accessories
Regulatory Class: II
Product code: FGB

III Predicate Devices

Trade name:	Karl Storz Flexible Video-Uretero-Renoscope System
Common name:	Ureteroscope and accessories, Flexible/Rigid
Classification:	Class II, 21 CFR 876.1500
Product Code:	FGB
Premarket Notification:	K131369

Trade name:	Boston Scientific Corporation LithoVue System
Common name:	Ureteroscope and accessories, Flexible/Rigid
Classification:	Class II, 21 CFR 876.1500
Product Code:	FGB
Premarket Notification:	K153049

IV Device description

The Ureterorenoscope System consists of a sterile single-use disposable Flexible Ureteroscope to be introduced within the urinary tract and endoscope operating system for clinical image processing.

V Device characteristics

The system consists of an EO sterilized single-use Flexible Ureteroscope and a non-sterile repeat use Video Processor. The Video processor is connected to mains power and provides power to the Flexible Ureteroscope.

The material inserted into the urine tract of the patient is TPU. The contact duration equals to the time of the Ureteroscopy, which is less than 24 hours. The biocompatibility of the material complies with ISO10993 series.

The device is intended to be used at hospitals or health clinics by trained physicians.

VI Operation principle

The Flexible Ureteroscope is inserted through the external urethral orifice and bladder during ureteroscopy. Anatomical images are transmitted to the user by the video processor with a CMOS chip at the distal end of the endoscope and the images showing on a monitor.

VII Indications for use

The Ureterorenoscope System consists of a sterile single-use disposable 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.

VIII Comparison of technological characteristics with the predicate devices

The Ureterorenoscope System has the same technological characteristics and fundamental design as the predicate devices. The Ureterorenoscope System and the predicate devices are all designed to provide real-time images to the physician in order to facilitate diagnostic and therapeutic procedures in the urinary tract. The differences between the Ureterorenoscope System and predicate devices do not alter suitability of the proposed device for its intended use.

IX Performance data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the Ureterorenoscope System was evaluated in accordance with ISO 10993-1:2009 for the body contact category of “Surface – Mucosal Membrane” with a contact duration of “Limited (< 24 hours)”. The following tests were performed, as recommended: Cytotoxicity, Irritation and Sensitization. All evaluation acceptance criteria were met

Sterilization and shelf life testing

The sterilization method has been validated to ISO11135, which has thereby determined

the routine control and monitoring parameters. The shelf life of the Flexible Ureterorenoscope is determined based on stability study which includes ageing test.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Ureterorenoscope System. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Optical performance testing

Optical performance testing was conducted on the Ureterorenoscope System. The optical performance of the system complies with ISO 8600 series.

Mechanical performance testing

Mechanical characteristics including leaking, bending, articulating and irrigation tests were performed.

X Conclusion

The Ureterorenoscope System is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed devices.