October 29, 2026

Zhejiang Geyi Medical Instrument Co., Ltd.
Cathy Tan
1, 2 Factory, # 5, Hutang Rd. Xiaya Town
Jiande City, Zhejiang 311606
CHINA

Re: K262437
Trade/Device Name: Single-use Digital Flexible Ureteroscope (GY-UR6.3);
Single-use Digital Flexible Ureteroscope (GY-UR6.3A)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: October 7, 2026
Received: October 8, 2026

Dear Cathy Tan:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administratio (FDA) may publish further announcements concerning your device in the Federal Register.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 R. Kreitz -S

for 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262437

Please provide the device trade name(s).

Single-use Digital Flexible Ureteroscope (GY-UR6.3);
Single-use Digital Flexible Ureteroscope (GY-UR6.3A)

Please provide your Indications for Use below.

Single-use Digital Flexible Ureteroscope 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

510(k) #: K262437

510(k) Summary

Prepared on: 2026-10-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zhejiang Geyi Medical Instrument Co.,Ltd.
Applicant Address	No. 1, 2 Factory, No. 5, Hutang Road Xiaya Town Jiande City Zhejiang 311606 China
Applicant Contact Telephone	+86 15158157854
Applicant Contact	Ms. Cathy Tan
Applicant Contact Email	lilyxu@zjgeyi.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Single-use Digital Flexible Ureteroscope (GY-UR6.3); Single-use Digital Flexible Ureteroscope (GY-UR6.3A)
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
K252468	single-use Digital Flexible Ureteroscope	FGB

Device Description Summary

21 CFR 807.92(a)(4)

The Single-Use Digital Flexible Ureteroscope system consists of Single-Use Digital Flexible Ureteroscope and Endoscope camera system. The Single-Use Digital Flexible Ureteroscope consists of an insertion part, an operating part, and an electrical connection part. The insertion part includes the distal tip, deflection section, insertion tube, CMOS module, LED light source, and the opening of the working channel. The tip is integrated with LED lighting source, 160,000 pixel CMOS image sensor and instrument channel tube with inner diameter of 1.0mm. During use, LED light source provides illumination, CMOS image sensor is used to collect image pixels of tissue parts, and instrument channel tube is used as the use channel of stone basket, holmium laser fiber, etc. Under the upper and lower 45° swing operation of the control lever, the upper and lower 275° swing Angle of the deflection section can be realized. The operation department is equipped with two functional shortcut keys, which have corresponding functions preset with the endoscope camera host. Press the key and the host will have corresponding functions. The Single-Use Digital Flexible Ureteroscope is powered by the Endoscope camera system. The electrical connection department transmits the image pixels obtained by the image sensor to the host, thus realizing the function of surgical imaging. The Endoscopic Camera System receives a video signal from a connected endoscope, controls the light from the tip of the endoscope and outputs that signal, including a graphical user interface, while presenting the image to the user.

Endoscope camera system consists of a portable image processor generator, Power flexible cable (1.5m) x1， Power adapter (cable 1.0m)x1， HDMI cable (2.0m)x1.

The Single-Use Digital Flexible Ureteroscope is provided sterile (sterilized by EO) and intended to be single-use. The Endoscope camera system is a reusable multi-patient use device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Single-use Digital Flexible Ureteroscope 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 indications for use are the same as K252468.

Technological Comparison 21 CFR 807.92(a)(6)

The device has the same product code, regulation number, indications for use, design, material, principle of operation, scope type (flexible), scope re-usability (single use), sterilization method (EO), illumination source (LED), active deflection in both directions (275°), working length(650mm), Field of View(120°), direction of view (0°) , Depth of Field(3-50mm), resolution (160,000 pixels)as the predicate device(s).

The proposed device is available in 2 models with maximum insertion widths of 2.4 mm, and minimum instrument channel widths of 1.0 mm, and the predicate device has maximum insertion widths of 3.2 mm, 3.0mm and 2.8 mm and minimum instrument channel widths of 1.2 mm and 1.0mm, respectively, which are smaller in maximum insertion widths and in minimum instrument channel widths compared to the predicate device. The proposed device utilizes CMOS (TA10), which differs from the CMOS (6946) incorporated in the predicate device. All the performance of proposed device was tested and the results met the standard requirements, this difference will not raise any issues in safety and effectiveness of the device.

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

The following performance testing was conducted using previously submitted methods and
acceptance criteria cleared under K252468 in support of the substantial equivalence, as shown in the table below.
The mechanical performance include following items:
☒Surface and edges
☒Maximum insert section width
☒Minimum Working channel width
☒Working length
☒Flow rate of water
☒Leak
☒Control lever
☒Maneuverability of surgical instruments in a bent state
☒Angle of deflection
Tensile testing
☒Torque testing
☒Fatigue testing

Comparative testing related to image quality parameters including following list was performed for proposed device and the predicate device to support substantial equivalence.:
☒Color performance
☒Field of view (FOV)
☒Direction of view (DOV)
☒Uniformity
☒Depth of field (DOF)
☒Resolution
☒Distortion
☒Signal-to-noise ratio (SNR)
☒Dynamic range

Shelf Life
Shelf life is determined based on stability study which includes ageing test according to ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Electrical safety and electromagnetic compatibility (EMC)
Electrical Safety and EMC data include in the submission meet the following standards.
☒IEC 60601-1:2012, and AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012
☒IEC 60601-2-18:2009: Part 2-18
☒IEC 60601-1-2:2014 and A1:2020

☒IEC TS 60601-4-2: 2024
☒AIM7351731 Rev.3.0
☒ANSI C63.18:2014

Based on the intended use/indications for use, comparison of key technological characteristics, and performance testing presented in this premarket notification demonstrated that the proposed is substantially equivalent to the currently marketed predicate device and can be safely and effectively used for its proposed indications.