December 16, 2025

Zhejiang Geyi Medical Instrument Co.,Ltd.
Cathy Tan
Director, Regulatory Affairs
No. 1, 2 Factory, No. 5, Hutang Road Xiaya Town
Jiande City, Zhejiang 311606
CHINA

Re: K252468
Trade/Device Name: Single-use Digital Flexible Ureteroscope (GY-UR9.3);
Single-use Digital Flexible Ureteroscope (GY-UR8.4);
Single-use Digital Flexible Ureteroscope (GY-UR7.5);
Endoscope camera system (GY-AIO-121)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Received: November 28, 2025

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: 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 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

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)*

K252468

Device Name

Single-use Digital Flexible Ureteroscope (GY-UR9.3);
Single-use Digital Flexible Ureteroscope (GY-UR8.4);
Single-use Digital Flexible Ureteroscope (GY-UR7.5);
Endoscope camera system (GY-AIO-121)

Indications for Use *(Describe)*

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.

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) #: K252468

510(k) Summary

Prepared on: 2025-12-12

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	tanzhongqin@zjgeyi.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Single-use Digital Flexible Ureteroscope (GY-UR9.3); Single-use Digital Flexible Ureteroscope (GY-UR8.4); Single-use Digital Flexible Ureteroscope (GY-UR7.5); Endoscope camera system (GY-AIO-121)
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
K172098	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.

Single-Use Digital Flexible Ureteroscope consists of a distal tip, a bending part, an insertion part, an operating part and an electrical connection part. The tip is integrated with LED lighting source, 160,000 pixel CMOS image sensor and instrument channel tube with inner diameter of 1.2mm or 1.1mm. 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 operating handle is equipped with two functional shortcut keys, which have corresponding functions preset with the endoscope camera host. The Single-Use Digital Flexible Ureteroscope is powered by the Endoscope camera system. The electrical connection part transmits the image pixels obtained by the image sensor to the host, thus realizing the function of surgical imaging. The Endoscope 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 similar. The subject device indications include more specific information regarding the anatomical locations within the urinary tract and route of access for which the device is intended to be used. These differences do not raise different questions of safety or effectiveness or alter the intended use compared to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The device has the same product code, regulation number, indications for use, application field, field of view, scope type (flexible), scope reusability (single use), ureteroscope is provided (sterile), sterilization (EO), imager type (CMOS), imager location (distal) , illumination source (LED), deflection (active and passive), direction of view (0°) , Depth of Field(3-50mm), resolution (160,000 pixels), design, material, principle of operation as the predicate device(s).

The degree of active deflection of the propose device is 275° in both directions, and the predicate device is 270° in both directions. The degree of active deflection of the proposed device is large than the predicate device.

The proposed device is available in 3 models with maximum insertion widths and minimum instrument channel widths of 3.2 mm and 1.2 mm, 3.0 mm and 1.2 mm, and 2.8 mm and 1.1 mm, respectively, and the predicate device has maximum insertion widths and minimum instrument channel widths of 3.2 mm and 1.0 mm, respectively, which are smaller in diameter and larger in width compared to the predicate device. The proposed device has a smaller insertion outer diameter and a larger instrument channel. The minimum insertion channel width of the proposed device is larger than that of the predicate device.

The working length of the propose device is 670mm, and the predicate device is 650mm. The working length of the proposed device is slightly longer than that of the predicate device.

These differences do not raise different questions of safety and effectiveness.

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

Sterilization and Shelf-Life:
Sterilization information was provided in accordance with the 2024 FDA guidance document, Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile. The sterilization process was validated according to ISO 11135:2014. The subject device shelf-life was supported by package integrity and performance testing conducted after accelerated aging (per ASTM F1980-21) and simulated shipping distribution (per ASTM D4169-22).

Biocompatibility:
Biocompatibility of the subject device was evaluated in accordance with the 2023 FDA guidance document, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" for the applicable endpoints of cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, and material-mediated pyrogenicity.

Software:
Software documentation was provided in accordance with the 2023 FDA guidance document, Content of Premarket Submissions for Device Software Functions.

Cybersecurity:
Cybersecurity information was reviewed in accordance with the 2023 FDA guidance document, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.

Electrical safety and electromagnetic compatibility (EMC)::
Electrical Safety and EMC data include in the submission meet the following standards.
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
IEC 60601-2-18:2009
IEC 60601-1-2:2020

Performance test was performed on the proposed device and predicate devices(K172098). Mechanical and optical performances were performed according to applicable part of ISO 8600 series standards, ISO 12233:2017 and ISO 15739:2017 standard.

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
- Luer connector
- 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

Photobiological safety:
The subject device was tested according to IEC 62471:2006 Medical electrical equipment, Photobiological safety of lamps and lamp systems.

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.