September 5, 2025

Zhejiang YiGao Medical Technology Co., Ltd.
Serena Zhou
Regulatory Manager
No.3, Gaoxin Jiu Road, Xiaoshan Economic and Technological
Development Zone
Hangzhou, 311200
China

Re: K250132
Trade/Device Name: Ureteral Access Sheath
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED
Dated: January 17, 2025
Received: July 31, 2025

Dear Serena Zhou:

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
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)*

K250132

Device Name

Ureteral Access Sheath

Indications for Use *(Describe)*

The ureteral access sheath is used to establish a working channel during endoscopic urological procedures, facilitating the passage of endoscopes and other instruments into the urinary tract.The intended population of this device should be adult only.
This is a single-use device. A re-sterilization by users and re-use of the device are not allowed.

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.***

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510(k) #: K250132

# 510(k) Summary

Prepared on: 2025-09-05

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Zhejiang YiGao Medical Technology Co., Ltd. |
| Applicant Address | No.3, Gaoxin Jiu Road, Xiaoshan Economic and Technological Development Zone Hangzhou, 311200 Zhejiang P.R. China Hangzhou 311200 China |
| Applicant Contact Telephone | 0571-86022937 |
| Applicant Contact | Ms. Serena Zhou |
| Applicant Contact Email | serena@yigaomedical.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Ureteral Access Sheath |
| Common Name | Endoscope and accessories |
| Classification Name | Endoscopic Access Overtube, Gastroenterology-Urology |
| Regulation Number | 876.1500 |
| Product Code(s) | FED |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K172217 | Flexor® Ureteral Access SheathFlexor® Parallel™ Rapid Releas | FED |

## Device Description Summary

21 CFR 807.92(a)(4)

The Ureteral Access Sheath consist of an outer sheath, a tapered dilator and their sockets. The hydrophilic coating are applied to the sheath and the tip of dilator.
The Ureteral Access Sheath is a single use sterile single-lumen access sheath, it contains two models of devices, FS and GS. The FS type can be avaliable with inner diameters ranging from 9 to 15 French and lengths ranging from 35 to 55 cm. and the GS type can be available with inner diameters ranging from 9 to 15 French, and lengths ranging form 20 to 55 cm.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ureteral access sheath is used to establish a working channel during endoscopic urological procedures, facilitating the passage of endoscopes and other instruments into the urinary tract.The intended population of this device should be adult only.
This is a single-use device. A re-sterilization by users and re-use of the device are not allowed.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has the same indication for use as the predicate devices.

## Technological Comparison

21 CFR 807.92(a)(6)

The proposed device and predicate device have the same intended use and indications, and also share the similar dimensions and technical characteristics.

The difference between predicate and the proposed device is the intended population,material used, sheath socket and the sheath tip.

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

The following bench tests were performed on this device: Tensile strength, Flexing resistance, smoothness, surface friction, guide wire passage, negative pressure performance, flexural properties, and X-ray detectability. The results of all testing were qualified.
The Sterilization process has been validated according to ISO 11135:2014, and the EO residual has also been evaluated according to ISO 10993-7:2008.
The device has a shelf life of 2 years, and been supported by the accelerate aging test. The package and transport validation has been validated to be effective according to ASTM D4169:2023 Standard Practice for Performance Testing of Shipping Containers and Systems (DC13), ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection, ASTM F88/88M-23, Standard Test Method for Sealing Strength of Flexible Barrier Materials, and ASTM F1929-23, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
The biocompatibility of the device has been well evaluated according to ISO 10993-1:2018. The device passed the Cytotoxicity(ISO 10993-5:2009), sensitization(ISO 10993-10:2021), irritation(ISO 10993-23:2021), acute systemic toxicity(ISO 10993-11:2017), and material mediated pyrogen evaluation(USP-NF Official as of 1-May-2017 General Chapter 151 Pyrogen test), demonstrated that the device's biocompatibility during use.

No clinical data is included in this submission.

The ureteral Access Sheath is substantially equivalent to predicate device. Based on the intended use, principle of operation, performance characteristics, technological characteristics and non-clinical tests performed, the proposed device is substantially equivalent to and as safe the as effective as the legally marketed predicate device.