July 8, 2025

Shenzhen HugeMed Medical Technical Development Co., Ltd.
Cathy Shi
Regulatory Engineer
401, 501, Building 4, Haizhi Technology Park, Fortis
No. 17 Bulan Road,Xialilang Community, Nanwan Street
Shenzhen, Guangdong 518112
China

Re: K250695
Trade/Device Name: Single-use Ureteral Access Sheath
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: May 5, 2025
Received: June 17, 2025

Dear Cathy Shi:

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
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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)*

K250695

Device Name

Single-use Ureteral Access Sheath

Indications for Use *(Describe)*

The Single-use Ureteral Access Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into 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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"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."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

I. Submitter

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401, 501, Building 4, Haizhi Technology Park, Fortis, No. 17, Bulan Road, Xialilang Community, Nanwan Street, Longgang District, Shenzhen, Guangdong, 518112, China

Date of preparation: Mar. 5, 2025

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II. Subject Device Information

Trade/Device Name: Single-use Ureteral Access Sheath
Common Name: Endoscope and accessories
Classification Name: Endoscopic Access Overtube
Regulation Name: Endoscope and accessories
Regulation Number: 21 CFR 876.1500
Regulatory Class: Class II
Product Code: FED
Panel: Gastroenterology/Urology
Submission type: Traditional 510(K)

III. Predicate Device

510(k) number: K241181
Product name: Disposable Ureteral Guide Sheath
Regulatory Class: Class II
Product Code: FED
Manufacturer: Dongguan ZSR Biomedical technology Company Limited

IV. Device Description

The Single-use Ureteral Access Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.
The device models are Y-09-40, Y-09-50, Y-10-40, Y-10-50, Y-11-40, Y-11-50, Y-12-40, and Y-12-50.
The device is composed of access sheath and dilator. The access sheath consists of sheath tube and connector. The dilator consists of dilator tube and dilator base. Single-use Ureteral Access Sheath is sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of 3 years.

V. Intended use & Indication for use

The Single-use Ureteral Access Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.

VI. Comparison to the Predicate Device

Characteristics	Subject Device	Predicate Device	Remark
K number	/	K241181	/
Product Code	FED	FED	Same
Regulation Description	Endoscope and accessories	Endoscope and accessories	Same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	Same
Regulatory Class	II	II	Same
Device trade name	Single-use Ureteral Access Sheath	Disposable Ureteral Guide Sheath	/
Indication for use/Intended use	The Single-use Ureteral Access Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.	The Disposable Ureteral Guide Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.	Same
Single use/ Reuse	Single-use	Single-use	Same
Sterile	Yes	Yes	Same
Sterilization Method	EO sterilization	EO sterilization	Same
Sheath ID	9Fr,10Fr, 11Fr, 12Fr	10Fr, 11Fr, 12Fr, 13Fr, 14Fr, 15Fr, 16Fr	Different 1
Sheath length	40cm, 50cm	10Fr, 11Fr, 12Fr, 13Fr, 14Fr:35cm, 40cm, 45cm, 50cm, 55cm 15Fr, 16Fr:40cm, 45cm	Different 2
Primary structure	The device is composed of access sheath and dilator. The access sheath consists of sheath tube and connector. The dilator consists of dilator tube and dilator base.	The device is composed of guide sheath and dilator. The guide sheath consists of guide sheath tube and connector.	Same

Materials	**Sheath tube**: Pebax, SUS304, PTFE **Sheath connector:** Polycarbonate (PC), Silicone, ABS, Polypropylene (PP) **Dilator tube**: polyethylene (PE) **Dilator base**: Polyoxymethylene (POM) **Hydrophilic coating**: Polyvinylpyrrolidone (PVP)	**Sheath tube**: Pebax, US304, PTFE **Connector**: polyamide (PA), silica gel **Dilator connector**: polypropylene (PP) **Dilator tube**: polyethylene (PE) **Hydrophilic coating**: Polyvinylpyrrolidone (PVP)	Different 3
Package	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same
Biocompatible	Yes	Yes	Same
Shelf Life	3 years	3 years	Same
Bending Resistance	The access sheath tube and the dilator tube were bent 90 ° in both directions by grasping the head and the tail. After 20 times of repetition, the tube body was free of cracks, creases, cracks and fractures, the coating was free of falling off, and the steel wire was not separated from the inner and outer rubber layers.	The guiding sheath tube and the dilating tube were bent 90 ° in both directions by grasping the head and the tail. After 20 times of repetition, the tube body was free of cracks, creases, cracks and fractures, the coating was free of falling off, and the steel wire was not separated from the inner and outer rubber layers.	Same
Friction Force	After being dipped in water, the surface is smooth, and the friction force is not more than 0.5 N; The average dynamic	After being dipped in water, the surface is smooth, and the friction force is not more than 0.5 N; The average dynamic	Same

	friction force of 10 repeated tests shall not be greater than 0.5 N.	friction force of 10 repeated tests shall not be greater than 0.5 N	
Peak tensile force	The peak tensile force between the sheath tube and sheath connector, and between the dilator tube and the dilator base shall be ≥ 20 N. The fracture force test shall be carried out when the sheath connector and the dilator base are locked. The minimum fracture force shall be ≥ 15N and shall not break for 15 s.	The joint between the guiding sheath tube and the tube body of the dilating tube and the connector shall be able to bear a force of ⩾ 20 N and shall not break for 15 s; The fracture force test shall be carried out when the guiding sheath tube connector and the expansion tube connector are locked. The minimum fracture force shall be ⩾ 15N and shall not break for 15 s.	Same

Different 1 – Sheath ID

This difference is in sheath ID. Different sheath inner diameter device will be selected by physician per patient's condition, this difference will not raise any issues in safety and effectiveness.

Different 2 – Sheath length

Different sheath length device will be selected by physician per patient's condition, this difference will not raise any issues in safety and effectiveness.

Different 3 – Materials

Biocompatibility of the Disposable Ureteral Guide Sheath was evaluated in accordance with the FDA guidance "Use of International Standard ISO 10993-1", this difference will not raise any issues in safety and effectiveness.

VII. Performance Data

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

Biocompatibility testing

Biocompatibility of the Single-use Ureteral Access Sheath was evaluated in accordance

with the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

1) Cytotoxicity
2) Sensitization
3) Irritation
4) Acute Systemic
5) Pyrogenicity

Sterility and Shelf -life

The Single-use Ureteral Access Sheath is provided sterile and its shelf-life is 3 years.
Sterilization Process has been validated accordance with ISO 11135:2014, ISO 11737-1:2018, ISO11737-2:2019.
EO/ECH residual test was performed according to ISO 10993-7:2008.
The shelf life is determined based on product performance testing after accelerated aging test according to ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
Package validation was conducted according to ASTM F1140/F1140M -13, ASTM F1886/F1886M-16, ASTM F88/F88M-23, ASTM F 1929-23.

Bench performance testing

The following bench Comparison tests were performed:
Appearance
Dimensions
Patency
Fitness
Seal leakage
Peak tensile force
Connection
Bending resistance
Deformation resistance
Suction
Friction
Flow rate
Ray detectability
Corrosion

VIII. Clinical study

Not applicable.

IX. Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.