June 27, 2025

CatheGenix (Xiamen) Co., Ltd.
Deyuan Zheng
Management Representative
Room 605-2A, No.37 Banshang, Building 2,
Torch Hi-Tech Zone, P.R.
Xiamen, Fujian 361000
CHINA

Re: K250585
Trade/Device Name: Lumena™ Ureteral Access Sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: May 28, 2025
Received: May 28, 2025

Dear Deyuan Zheng:

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)*

K250585

Device Name

LumenaTM Ureteral Access Sheath

Indications for Use *(Describe)*

The LumenaTM Ureteral Access Sheath is indicated 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

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510(k) Summary

1. Submitter's Information

Sponsor: CatheGenix (Xiamen) Co., Ltd.
Room 605-2A, No.37 Banshang, Building 2, Torch Hi-Tech Zone, Xiamen 361000, P.R. China

Contact: Deyuan Zheng
CatheGenix (Xiamen) Co., Ltd.
Management representative
86+15201818268

Date Prepared: February 21, 2025

2. Identification of Proposed Device

Trade Name:	Lumena™ Ureteral Access Sheath
Common Name:	Ureteral Access Sheath
Classification Name:	Endoscopic access overtube
Classification Regulation:	21 CFR 876.1500
Product Code:	FED
Device Class:	2

3. Identification of Predicate Devices

Disposable Ureteral Guide Sheath cleared under K241181.

4. Intended Use/Indications for Use

The ureteral access sheath is indicated to establish a conduit during endoscopic urological procedures, facilitating the passage of endoscopes and other instruments into the urinary tract.

5. Device Description

The Lumena™ Ureteral Access Sheaths are designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures. The sheaths are available with both a bendable tip with a Y-shape joint on the proximal end and a straight tip with the outside diameters ranging from 11 to 15 French and lengths ranging from 35 to 45 centimeters. These devices are available in a single lumen configuration and include a sheath tube and a dilator. The bendable-tip sheath is intended to be connected to a negative pressure aspirator for the collection of stones or foreign bodies during the endoscopic procedure.

6. Comparison to Predicate Devices

The subject device is substantially equivalent to the predicate devices as they share the same indications for use and similar technological characteristics. Technological

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characteristics of the subject device compared to each predicate is shown in the following table.

Table 1. General Comparison

Technological Characteristics	**Proposed Device**	**Predicate Device** Disposable Ureteral Guide Sheath**[K241181]**
Manufacturer	CatheGenix (Xiamen) Co., Ltd.	Dongguan ZSR Biomedical Technology Company Limited
Regulation Number	21 CFR 876.1500	21 CFR 876.1500
Product Code	FED	FED
Classification Name	Endoscope and accessories	Endoscope and accessories
Classification	Class 2	Class 2
Intended Use /Indications for Use	The ureteral access sheath is indicated 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.
Sterility	Yes, 10^{-6}	Yes, 10^{-6}
Sterilization method	Eto sterilized	Eto sterilized
Single Use	Yes	Yes
Sheath ID	9.5Fr, 11Fr, 12Fr, 13Fr	10Fr, 11Fr, 12Fr, 13Fr, 14Fr, 15Fr, 16Fr,
Sheath length	9.5Fr, 11Fr, 12Fr, 13Fr: 35cm, 40cm, 45cm	10Fr, 11Fr, 12Fr, 13Fr, 14Fr:35cm, 40cm, 45cm 15Fr, 16Fr:40cm, 45cm
Primary structure	The device is composed of sheath and dilator. The sheath consists of sheath tube and connector (straight, Y-shaped).	The device is composed of guide sheath and dilator. The guide sheath consists of guide sheath tube and connector (straight, Y-shaped, W-shaped and cross-shaped).

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Technological Characteristics	**Proposed Device**	**Predicate Device** Disposable Ureteral Guide Sheath**[K241181]**
Materials	**Sheath tube:** PEBAX, SUS304, PTFE **Sheath connector:** Polycarbonate (PC), Silicone **Dilator connector:** polypropylene (PP) **Dilator tube**: Polyethylene (PE) **Hydrophilic coating:** Polyvinylpyrrolidone (PVP)	**Sheath tube:** Pebax, SUS304, PTFE **Connector:** Polyamide (PA), silica gel **Dilator connector:** polypropylene (PP) **Dilator tube:** Polyethylene (PE) **Hydrophilic coating:** Polyvinylpyrrolidone (PVP)
Package	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch
Biocompatible	Yes	Yes

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7. Summary of Non-Clinical Performance Data

Bench testing was performed to establish substantial equivalence to the predicates and to demonstrate that the subject device will perform as intended. All the testing results meet the defined acceptance criteria. Detailed testing conducted are as follows:

- Tensile Performance Test
- Hydrophilic Coating Performance Test
- Luer Connector Performance Test
- Compatibility Performance Test
- Bending-Resistance Test
- Negative Pressure Suction Test
- Adhesion performance of marks Test
- Radiopacity Test

Sterilization validation of Lumena™ Ureteral Access Sheath was carried out in accordance with ISO 11135:2014+A1:2018 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices".

Packaging & Shelf-life testing was conducted based on an accelerated aging test in accordance with:

- ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 11607-1:2019: Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019: Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes.

Accelerated aging test was performed to demonstrate the device's stability during its claimed shelf life.

Biocompatibility evaluation for the Lumena™ Ureteral Access Sheath was conducted in accordance with FDA Guidance, Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" (September 8, 2023), the following tests were conducted:

a) Cytotoxicity
b) Sensitization
c) Irritation
d) Acute System Toxicity
e) Pyrogen

8. Summary of Clinical Test

No clinical study is included in this submission.

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9. Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the Lumena™ Ureteral Access Sheath has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate devices:

(1) Disposable Ureteral Guide Sheath cleared under K241181;