March 26, 2025

Shenzhen Trious Medical Technology Co., Ltd
% Kyra Kang
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd
Room 1308, Baohua International Plaza, West Guangzhong Road
Shanghai, Jingan District
CHINA

Re: K243710
Trade/Device Name: Disposable ureteral access sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: December 2, 2024
Received: March 12, 2025

Dear Kyra Kang:

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)*

K243710

Device Name

Disposable Ureteral Access Sheath

Indications for Use *(Describe)*

The Disposable Ureteral Access Sheath is used to establish a continuous conduit during urological endoscopic procedures facilitating the in and out 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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510(k) Summary

I. Submitter

Shenzhen Trious Medical Technology Co., Ltd
Rm 102-2, Longtian Tongfuyu Ind Estate #11-3, and Rm 401 & 402, Bldg D3, YingZhan S&T Estate, Longtian Tongfuyu Rd #8; Longtian Com, Longtian St, Pingshan, Shenzhen, GD, China
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Tel.: 0086-13424218407
E-mail: trsyl@trious.cn

Preparation date: March 25, 2025

Submission Correspondent
Ms. Kyra Kang
Landlink Healthcare Technology (Shanghai) Co., Ltd.
E-mail: kyra.kang@landlink-health.com

II. Proposed Device

Device Trade Name:	Disposable Ureteral Access Sheath
Common name:	Endoscopic Access Overtube
Classification Name:	Endoscope and accessories (21 CFR 876.1500)
Regulatory Class:	Class II
Product code:	FED
Review Panel:	Gastroenterology/Urology

III. Predicate Devices

510(k) Number:	K230748
Trade name:	Disposable Ureteral Access Sheath
Common name:	Endoscopic Access Overtube
Regulatory Class:	Class II
Product Code:	FED
Manufacturer	YouCare Technology Co., Ltd. (Wuhan).

This predicate has not been subject to a design-related recall.

IV. Device description

The proposed device, Disposable Ureteral Access Sheath is used to establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.
This device is divided into five types:

- Z type Straight joint access sheath
- Y type negative suction Y joint access sheath
- W type negative suction Y joint access sheath
- T type Straight joint access sheath
- C type negative suction W joint access sheath

This product consists of access sheath and dilator tube. The access sheath tube consists of access sheath tube body and access sheath joint. The surface of access sheath tube is coated with polyvidone (PVP). The dilator tube consists of dilator tube body and dilator tube connector. The access sheath tube body is made from nylon (PA), stainless steel and polytetrafluoroethylene (PTFE). The access sheath joint is made from polycarbonate (PC), acrylonitrile-butadiene-styrene copolymer (ABS) and silicone. The dilator tube body and dilator tube connector are made from PE.

The proposed devices are 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. Indications for use

The Disposable Ureteral Access Sheath is used to establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.

VI. Comparison of technological characteristics with the predicate devices

Table 1 General Comparison of Disposable Ureteral Access Sheath

Characteristics	Proposed device	Predicate device (K230748)	Discussion
Manufacturer	Shenzhen Trious Medical Technology Co. Ltd	YouCare Technology Co., Ltd. (Wuhan)	/
Regulation #	876.1500	876.1500	Same
Product code	FED	FED	Same
Classification name	Endoscope and accessories	Endoscope and accessories	Same
Intended use	The Disposable Ureteral Access Sheath is used to	The Disposable Ureteral Access Sheath is used to establish a conduit during	Same

	establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.	endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract	
Regulatory Class	Class II	Class II	Same
Sterility	Yes	Yes	Same
Sterilization Method	EO	EO	Same
Single Use	Yes	Yes	Same
Sheath ID	10Fr, 11Fr, 12Fr, 13Fr, 14Fr	12Fr	Different 1
Sheath length	35cm, 40cm, 45cm, 50cm	45cm, 35cm	Different 2
Primary structure	This product consists of access sheath and dilator tube. Z-type access sheath and T-type access sheath consist of tube body and straight joint; Y-type access sheath and W-type access sheath consist of tube body, Y-type joint and end cap; C type access sheath consists of tube body, W-type joint and end cap; the dilator tube consists of tube body and joint.	The product is composed of sheath tube, sheath tube base, dilator and center base of dilator. The sheath tube base contains a backwater interface. The center base of dilator consists of upper cover of dilator base, lower cover of dilator base, fiber image channel interface F, irrigation channel interface I, equipment channel interface E, obturator, two-way water valve, needle free joint.	Similar 3
Materials	Access sheath Tube body ：PEBAX 6333 SA 01 MED, SUS 304, PTFE Access sheath joint**:** ABS, PC (Pressure valve: ABS) Silicone cap: silicone Access sheath Tube body Coating: PVP Dilator tube body: LDPE Dilator tube connector: HDPE	**sheath tube:** Pebax6333 SA01 MED, SUS 304, PTFE, PAM **sheath tube base:** ABS, PC (backwater interface: PC) **dilator:** LDPE **center base of dilator** **upper cover of the dilator base**: ABS **lower cover of the dilator base:** ABS **fiber image channel interface F:** PC **irrigation channel interface I:** PC **equipment channel interface E:** PC	Similar 4

		obturator: PC, silica gel **two-way water valve:** PC, POM **needle-free joint:** PC, silica gel	
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	Fix the head end of the access sheath tube, dilator tube on a cylinder former with a radius of 5cm.wind the access sheath around the cylinder former for one circle ring and keep it for l min. Then release the wound access sheath tube. The tube body of the access sheath should remain intact without any deformations, cracks, folding, or other defective phenomena.	Bending any section of the dilator, sheath tube or the assembly of sheath tube and dilator into a ring with a radius of 5cm for 1min, there should be no crease, crack or other undesirable phenomena.	Same
Coefficients of Friction	When the sheath tube is tested for friction, the friction coefficient shall not exceed 0.03.	When the sheath tube is tested for friction, the friction coefficient shall not exceed 0.03.	Same
Peak tensile force	The minimum peak tensile force at the access sheath tube body, and at union of the access sheath tube body and the access sheath tube joint shall not be less than 15 N.	The peak tensile force of the sheath tube and dilator should not be less than 15N. And the peak tensile force of the junction between sheath tube and sheath tube base, the dilator and center base of dilator also shall meet the requirement.	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 new questions of 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 new questions of safety and effectiveness.

Similar 3 – Primary structure

The predicate device has three instrument channels--- image channel, irrigation channel and equipment channel, it only increases the operation requirements for doctors. All the performance of the proposed device was tested, and the results met the standard requirements, this difference will not raise new questions of safety and effectiveness.

Similar 4 – Materials

Biocompatibility of the Disposable Ureteral Access Sheath was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1”, this difference will not new questions of safety and effectiveness.

VII. Non-Clinical Testing

The device described in this summary Disposable Ureteral Access Sheath, were tested and demonstrated to be in conformance with the following standards:

Performance testing：

A series of performance tests were conducted on the device.

	Items
Whole device	Appearance
	Dimension
Access sheath tube	Liquid leakage
	Peak tensile force
	Friction coefficient
	Toughness
	Resistance To Flattening
Dilator tube	Strength of union of the dilator tube connector and dilator tube
	Resistance to flexing
	Compatibility
	Trafficability
	Dilator tube connector

Biocompatibility testing

Biocompatibility of the Disposable Ureteral Guide Sheath was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1” The following testing was conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic
- Pyrogenicity

Sterility and Shelf -life

- ISO 11135:2014
- ISO 11737-1:2018
- ISO11737-2:2019
- ISO 10993-7: 2008
- ASTM F1980-2016
- ASTM D3078-02-2021
- ASTMF 1929-15
- ASTM F88/F88M-15

VIII. Clinical Testing

No clinical study is included in this submission.

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 as safe and effective as the predicate device. Accordingly, the proposed device is substantially equivalent to the predicate device.