May 14, 2025

Shenzhen Trious Medical Technology Co., Ltd
% Kyra Kang
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd
Room 1308, Baohua International Plaza,
West Guangzhong Road 555, Jingan District
Shanghai,
CHINA

Re: K243830
Trade/Device Name: Disposable Ureteral Stent
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: April 11, 2025
Received: April 14, 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,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
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.

510(k) Number *(if known)*
K243830

Device Name
Disposable ureteral stent

Indications for Use *(Describe)*
The Disposable ureteral stent is intended for temporary drainage from the ureteropelvic junction to the bladder of the ureter in a variety of benign, malignant and post-traumatic conditions of the ureter. These conditions include stones and/or stone fragments or other ureteral obstructions such as those associated with ureteral stricture, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma, or in association with Extracorporeal Shock Wave Lithotripsy (ESWL). The stent should be placed using endoscopic surgical technique. The stent is not intended as a permanent indwelling device. The indwelling time should not exceed thirty (30) days.
The 4Fr model is intended to be used for pediatric (adolescents, children, and infants) patients.

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) Summary

1. Submitter Information

510 (k) submitter	Shenzhen Trious Medical Technology Co., Ltd
Address	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, Guangdong, China
Contact Person	Yi Yingfang Registration Specialist Phone: 0086-13424218407 Email: trsyl@trious.cn
Submission Correspondent	Ms. Kyra Kang Landlink Healthcare Technology (Shanghai) Co., Ltd. Email: kyra.kang@landlink-health.com
Preparation Date	May 12, 2025

2. Device Name

Trade Name of the Device	Disposable ureteral stent
Common Name	Ureteral Stent
Classification Name	Stent, Ureteral
Classification Regulation	21 CFR 876.4620
Device Class	Class II
Panel	Gastroenterology/Urology
Product Code	FAD

3. Predicate and Reference Devices

Predicate Device:

510(k) Number	K213444
510(k) Holder	Ureteral Stent Company, Inc.
Trade Name of the Device	RELIEF Ureteral Stent Kit; Model: RS-001 - 6 Fr x 24cm RELIEF Ureteral Stent Kit; Model: RS-002 - 6 Fr x 26cm
Classification Name	Stent, Ureteral

Regulation Classification	21 CFR 876.4620
Device Class	Class II
Panel	Gastroenterology/Urology
Product Code	FAD

Reference Device

510(k) Number	K161236
Owner	Cook Medical Inc.
Trade Name of the Device	Universa Firm Ureteral Stents and Stent Sets
Classification Name	Stent, Ureteral
Regulation Classification	21 CFR 876.4620
Device Class	Class II
Panel	Gastroenterology/Urology
Product Code	FAD

4. Device Description

Disposable ureteral stents are sterile, single-use devices, that are inserted into the ureter endoscopically to facilitate the drainage of urine from the kidney to the bladder and can be used for treatment of ureter blockage and stricture.

The stents are available in 4.0 to 12.0 French (Fr) diameter, with lengths ranging from 12.0 to 30.0 centimeters (cm). The device includes a polyurethane stent, a push catheter, and optional accessories - a guide wire (coated guide wire, hydrophilic guide wire, or zebra guide wire) and a guide wire sheath.

The stents include Type A, C, D, F, and H stents all of which are composed of tube bodies only. The stents are secured in the urinary tract with pigtail loops on the proximal (renal pelvis) and distal (bladder) ends.

The Disposable ureteral stents are not intended as a permanent indwelling device and is labeled for indwell time not to exceed thirty (30) days only.

5. Indication for use

The Disposable ureteral stent is intended for temporary drainage from the ureteropelvic junction to the bladder of the ureter in a variety of benign, malignant and post-traumatic conditions of the ureter. These conditions include stones and/or stone fragments or other ureteral obstructions such as those associated with ureteral stricture, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma, or in association with Extracorporeal Shock Wave Lithotripsy (ESWL). The stent should be placed using endoscopic surgical technique.

The stent is not intended as a permanent indwelling device. The indwelling time should not exceed thirty (30) days.

The 4Fr model is intended to be used for pediatric (adolescents, children, and infants) patients.

6. Comparison of technological characteristics with the predicate & reference devices

Device Characteristics	K243830 Subject Device	K213444 Predicate device	K161236 Reference Device
Manufacturer	Shenzhen Trious Medical Technology Co., Ltd	Ureteral Stent Company, Inc.	Cook Medical Inc.
Regulation #	876.4620	876.4620	876.4620
Product code	FAD	FAD	FAD
Classification name	II	II	II
Intended use	The Disposable ureteral stent is intended for temporary drainage from the ureteropelvic junction to the bladder of the ureter in a variety of benign, malignant and post-traumatic conditions of the ureter. These conditions include stones and/or stone fragments or other ureteral obstructions such as those associated with ureteral stricture, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma, or in association with Extracorporeal Shock Wave Lithotripsy (ESWL). The stent should be placed using endoscopic surgical technique. The stent is not intended as a permanent indwelling device. The indwelling time should not exceed thirty (30) days. The 4Fr model is intended to be used for pediatric (adolescents, children, and infants) patients.	The RELIEF™ Ureteral Stent is intended for temporary drainage from the ureteropelvic junction to the bladder of the ureter in a variety of benign, malignant and post-traumatic conditions of the ureter. These conditions include stones and/or stone fragments or other ureteral obstructions such as those associated with ureteral stricture, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma, or in association with Extracorporeal Shock Wave Lithotripsy (ESWL). The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic technique. The stent is not intended as a permanent indwelling device. The indwelling time should not exceed thirty (30) days.	The Universa® Firm Ureteral Stents and Stent Sets are intended for temporary internal drainage from the ureteropelvic junction to the bladder. Ureteral stents have been used to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. The stents may be placed using endoscopic, percutaneous, or open surgical techniques.
Indwell Time	Not to exceed thirty (30) days.	Not to exceed thirty (30) days.	For a 12-month indwell time
Diameter	4Fr, 5 Fr, 6 Fr, 7 Fr, 8 Fr	6 Fr	4, 6, and 8 Fr
Length	12cm, 14cm, 16cm, 18cm, 20cm, 22cm, 24cm, 26cm, 28cm, 30cm	24cm, 26cm	20cm, 22cm, 24cm, 26cm, 28cm
Proximal Coil	Part of the stent body	Part of the stent body	Part of the stent body

Bladder Coil	Part of the stent body	Distal Coil attached to a distal tether	Braided or monofilament tether on distal pigtail loop
Guidewire	4Fr stents accept 0.028” guide wire; 5Fr & 6Fr stents accept 0.032” guide wire; 7Fr & 8Frstents accept 0.035” guide wire	6.0 Fr stents accept 0.035″ and 0.038″ guide wire	6.0 Fr stents accept 0.038″ guide wire
Push Tube	Push tube without radiopaque tip	Push Tube with radiopaque tip	Stent Positioner with radiopaque tip
Pigtail Straightener	No	Yes	Yes
Sterilization	EtO	EtO	EtO
Single use	Yes	Yes	Yes

As evidenced by the above table, both the subject and predicate devices have similar intended use, but they have different technological characteristics. Performance testing was conducted on the subject stents, and it was established that the differences in technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness.

7. Non-Clinical Testing

Disposable ureteral stents were tested and demonstrated to equivalent to the predicate device in safety and performance:

Bench testing:
A battery of bench testing based on the FDA guidance “Guidance for the Content of Premarket Notification for Ureteral Stents"(1993) was conducted on the subject stents using established methods and standards to demonstrate the performance substantial equivalence to the predicate and reference devices.

Biocompatibility testing:
Biocompatibility of the Disposable ureteral stent 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 Toxicity
- Material-Mediated Pyrogenicity
- Subacute/Subchronic Toxicity
- Implantation

Sterility and Shelf-life:
The subject device is sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} (ISO 11135:2014) and the device packaging was tested for integrity in maintaining a sterile barrier over a shelf life of 3 years. An accelerated aging study and simulated transportation

study were conducted on each type of stent to demonstrate that each stent type was able to maintain the device performance over a shelf life of 3 years.

8. Clinical Testing

No clinical study is included in this submission.

9. 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. Therefore, the subject device is substantially equivalent to the predicate device.