February 20, 2026

Zhejiang Chuangxiang Medical Technology Co., LTD.
Lucius Long
RA Manager
Room 101-1, 201-1, 301, 401, Building 50
No.650 Hongfeng Road, Donghu Street, Linping District
Hangzhou, 311100
CHINA

Re: K251890
Trade/Device Name: Disposable Ureteral Stents (Types C and D)
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: January 20, 2026
Received: January 20, 2026

Dear Lucius Long:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Negeen Haghighi -S

for
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)*
K251890

Device Name
Disposable Ureteral Stents (Types C and D)

Indications for Use *(Describe)*
The Disposable Ureteral Stents are used 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 are placed using endoscopic technique. The indwelling time should not exceed 30 days.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

I. Submitter information

510(k) Submitter:	Zhejiang Chuangxiang Medical Technology Co., LTD.
Address:	Room 101-1, 201-1, 301 & 401, Building 50 No.650 Hongfeng Road, Donghu Street Linping District, Hangzhou, 311100 Zhejiang Province, P.R. China
Contact Person:	Lucius Long Telephone: 86-571-89167088 Fax: 86-571-89167086 Email： lucius.long@med-nova.com
Preparation Date:	February 19, 2026

II. Subject Device

Common Name:	Ureteral Stent
Trade Name of Device:	Disposable Ureteral Stents (Types C and D)
Classification Name:	Stent, Ureteral
Regulation Class:	Class II
Regulation Number:	21 CFR 876.4620
Review Panel:	Gastroenterology/Urology
Product Code:	FAD

III. Predicative and Reference Devices

Predicate Device:

510(k) Number:	K161236
510(k) Holder:	Cook Incorporated
Trade Name of Device:	Universa™ Firm Ureteral Stents and Stents Sets
Classification Name:	Stent, Ureteral
Regulation Class:	Class II
Regulation Number:	21 CFR 876.4620
Review Panel:	Gastroenterology/Urology
Product Code:	FAD

Reference Device:

510(k) Number:	K243830
510(k) Holder:	Shenzhen Trious Medical Technology Co., Ltd
Trade Name of Device:	Disposable Ureteral Stent
Classification Name:	Stent, Ureteral
Regulation Class:	Class II
Regulation Number:	21 CFR 876.4620
Review Panel:	Gastroenterology/Urology
Product Code:	FAD

IV. Device Description

The Disposable Ureteral Stents are a set of ureteral stents used for temporary internal drainage from the ureteropelvic junction to the bladder. The subject ureteral stent is a flexible, tubular double pigtail stent composed of radiopaque polycarbonate-based polyurethane with hydrophilic coating. The subject stents include two stent types: Type C and Type D stents. The only difference between the two types of stents is the opening at the stent end (Type C - single opening at one end only vs. Type D - double openings with one at each end).

The Disposable Ureteral Stents are available in 4.0 to 8.0 French (Fr) diameter, with lengths ranging from 14.0 to 28.0 centimeters (cm) (4Fr × 14 cm for pediatric patients and other sizes for adults). The stents are supplied sterile, packaged with a small pusher tube. Depending on configurations, the device package may include an optional guide wire, clamp or silk thread in addition to the stent and pusher tube.

The Disposable Ureteral Stents are not intended for long-term use. The stents are labeled for indwell time not to exceed thirty (30) days and no repeated use. The Silk thread should be removed after 14 days.

V. Indications for Use

The Disposable Ureteral Stents are used 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 are placed using endoscopic technique. The indwelling time should not exceed 30 days.

VI. Comparison of Technological Characteristics with Predicate Device

Device Characteristics	K251890 Disposable Ureteral Stents (Types C and D) (Subject Device)	K161236 Universa™ Firm Ureteral Stents and Stent Sets (Predicate Device)
Manufacturer	Zhejiang Chuangxiang Medical Technology Co., LTD.	Cook Incorporated
Regulation No.	21 CFR 876.4620	21 CFR 876.4620
Product Code	FAD	FAD
Classification	Class II	Class II
Indications For Use	The Disposable Ureteral Stents are used 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 are placed using endoscopic technique. The indwelling time should not exceed 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.
Labeled Indwelling Time	• Not to exceed thirty (30) days for stent • Thread removed after 14 days	• Not to exceed 12 months for stent • Tether removed after 14 days
Device Components	• Double pigtail ureteral plastic stent (radiopaque marks) • Pusher tube • Guidewire (optional) • Clamp (optional) • Thread (optional)	• Double pigtail ureteral plastic stent (radiopaque marks) with tethers and pigtail straightener. • Positioner with radiopaque tip • Guidewire
Stent Material	Polyurethane Hydrophilic coating	Polyurethane Hydrophilic coating
Stent Diameter*	4.0Fr, 4.5Fr, 4.7Fr, 5.0Fr, 6.0Fr, 7.0Fr, 8.0Fr	5.0Fr, 6.0Fr, 7.0Fr, 8.0Fr
Stent Length (cm)	14, 16, 18, 20, 22, 24, 26, 28 cm	18, 20, 22, 24, 26, 28, 30, 32 cm
Stent Coils	Double pigtails (one at each end)	Double pigtails (one at each end)
Pusher Tube/Positioner	• Diameter: 4.0Fr, 4.8Fr, 6.3Fr • Length: 70, 60, 40cm	• Diameter: 5Fr, 6Fr, 7Fr, 8Fr • Length: not specified
Guide Wire	• Diameter: 0.028'' for 4.0Fr and 4.5Fr; 0.032'' for 4.7Fr and	• Diameter: 0.035" for 5Fr; 0.038" for 6Fr, 7 Fr and 8 Fr

	5.0Fr; 0.035'' for 6.0Fr, 7.0Fr and 8.0Fr • Length: 150 cm	• Length: not specified
Sterilization	EtO	EtO
Single Use	Yes	Yes

*The 4.0Fr stent is intended for pediatric patients and the reference device includes this size.

As evidenced by the above table, both the subject and predicate devices have similar intended use, but they have different technological characteristics. Non-clinical 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.

VII. Non-Clinical Data

The Disposable Ureteral Stents were tested and demonstrated to be substantially equivalent to the predicate device in safety and performance.

Biocompatibility Testing:

Biocompatibility of the Disposable Ureteral Stents 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'" (September 4, 2020). The following biological endpoints were addressed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Subacute Systemic Toxicity
- Muscle Implantation
- Genotoxicity

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 2 years. An accelerated aging study and simulated transportation study were conducted on representative device models to demonstrate that the subject device was able to maintain the device performance over a shelf life of 2 years.

Bench Performance Testing:

A battery of bench testing based on the FDA guidance “Guidance for the Content of Premarket Notification for Ureteral Stents” (1993) and ASTM 1828-22 “Standard specification for ureteral stents” was conducted on the subject and predicate stents using established methods to demonstrate the substantial equivalence to the predicate device.

The performance evaluations included:

- Appearance and dimensions
- Flow rate
- Break strength and elongation
- Pigtail retention strength
- Dynamic frictional force
- Ink adherence
- Guidewire performance and compatibility
- Pusher tube performance and compatibility
- Clamp strength
- Silk thread strength and attachment performance

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusions

The proposed device has the similar indications for use and has similar design features and technological characteristic as the predicate device. Non-clinical 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 Universa™ Firm Ureteral Stents and Stents Sets.