June 18, 2025

Alton (Shanghai) Medical Instruments Co. Ltd
Wei Song
Project Engineer
No.24 Building, Jinshao Rd. 1688, Baoshan District
Shanghai 200949
CHINA

Re: K243039
Trade/Device Name: Ureteral Stents (AF-D series)
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: Class II
Product Code: FAD
Dated: May 23, 2025
Received: May 23, 2025

Dear Wei Song:

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,

Angel A. Soler-garcia -S

for
Jessica 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)*
K243039

Device Name
Ureteral Stents (AF-D series)

Indications for Use *(Describe)*
Ureteral Stents (AF-D series) 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 may be placed using endoscopic, percutaneous, or open surgical techniques. 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:	Alton (Shanghai) Medical Instruments Co. Ltd.
Address:	No.24 Building, JinShao Rd. 1688, Baoshan District, 200949 Shanghai, P. R. China
Contact Person:	Vivian Li Director of Quality Phone: (+86) 21-56771811 Fax: (+86) 21-66307823 Mail: vivian@alton.com.cn
Preparation Date:	June 15, 2025

II. Subject Device

Trade Name of Device:	Ureteral Stents (AF-D series)
Classification Name:	Stent, Ureteral
Regulation Number:	21 CFR 876.4620
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Product Code:	FAD

III. Predicate and Reference Devices

Predicate Device:

510(k) Number:	K151051
510(k) Holder:	Cook Incorporated
Trade Name of Device:	Universa Soft Ureteral Stents and Stent Sets
Classification Name:	Stent, Ureteral
Regulation Number:	21 CFR 876.4620
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Product Code:	FAD

Reference Device:

510(k) Number:	K190659
Trade Name of Device:	Pediatric Ureteral Stent Open Tip/Closed Tip
Classification Name:	Stent, Ureteral
Regulation Number:	21 CFR 876.4620
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Product Code: FAD

IV. Device Description

Ureteral Stents (AF-D series) 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 thermoplastic polyurethane with hydrophilic coating. Depending on configurations, the device may include a ureteral stent only, or a stent with an introducer and a clamp, or a stent with an introducer, a guidewire and a clamp.

Ureteral Stents are available in 4.0 to 7.0 French (Fr) diameter, with lengths ranging from 8.0 to 28.0 centimeters (cm). The device is supplied sterile, intended for single use only, and is available for prescription use only.

Ureteral Stents are not intended as a permanent indwelling device. The subject stent is labeled for indwell time not to exceed thirty (30) days only.

V. Indications for Use

Ureteral Stents (AF-D series) 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 may be placed using endoscopic, percutaneous, or open surgical techniques. The indwelling time should not exceed 30 days.

VI. Comparison of Technological Characteristics with Predicate Device

Device Characteristics	**K243039** **Ureteral Stents (AF-D series)** ***(Subject Device)***	**K151051** **Universa Soft Ureteral Stents and Stent Sets** ***(Predicate device)***
Manufacturer	Alton (Shanghai) Medical Instruments Co., Ltd.	Cook Incorporated
Regulation No.	876.4620	876.4620
Product Code	FAD	FAD
Classification	Class II	Class II
Indications for Use	Ureteral Stents (AF-D series) 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 may be placed using endoscopic, percutaneous, or open surgical techniques. The indwelling time should not exceed 30 days.	The Universa Soft Ureteral Stents and Stent Sets 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 may be placed using endoscopic, percutaneous, or open surgical techniques.
Surgical Technique	• Stent is visible under fluoroscopy. • Stent placement via endoscopic, percutaneous or open surgical techniques.	• Stent is visible under fluoroscopy. • Stent placement via endoscopic, percutaneous or open surgical techniques.

Indwell Time	Not to exceed thirty (30) days.	For a 6-month indwell time
General Technological Characteristics		
Device Configurations	• Ureteral Stent only • Ureteral Stent + Introducer + Clamp • Ureteral Stent + Introducer + Guide Wire + Clamp	• Ureteral Stent only • Ureteral Stent + Positioner • Ureteral Stent + Positioner + Guide wire
Other Components	No	• A suture tether attached to the proximal pigtail of the stent. • A pigtail straightener
Stent Diameter	4Fr, 5Fr, 6Fr, 7Fr	5Fr, 6Fr, 7Fr, 8Fr
Stent Length	8.0cm, 10cm, 12cm, 14cm, 16cm, 18cm, 20cm, 22cm, 24cm, 26cm, 28cm	8-30 cm
Stent Coils	Double pigtails	Double pigtails
Introducer or Positioner	• Diameter: 4Fr, 5Fr, 6Fr, 7Fr • Length: 60cm	• Diameter: 5Fr, 6Fr, 7Fr, 8Fr • Length: Not identified
Characteristics of Introducer/Positioner	No radiopaque tip	With a radiopaque tip
Guidewire	• Diameter: 0.025″ for 4Fr/5Fr stents; 0.035″ for 6Fr/7Fr stents • Length: 15cm	• Diameter: 0.035″ for 5Fr stent; 0.038″ for 6Fr/7Fr/8Fr stents • Length: Not specified.
Sterilization	EtO	EtO
Single use	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.

VII. Non-Clinical Data

Ureteral Stents (AF-D series) were tested and demonstrated to be equivalent to the predicate device in safety and performance.

Biocompatibility Testing:

Biocompatibility of 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 biocompatibility testing was conducted:

- 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 3 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 3 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) was conducted on the subject, predicate and reference stents using established methods and standards to demonstrate the performance substantial equivalence to the predicate device. The reference device was used to support the function and performance of the 4Fr pediatric configuration in the subject device.

The performance evaluations included:

- Appearance and Dimensions
- Curl Retention Test (pigtails)
- Break Strength & Elongation
- Flow Rate
- Dynamic Friction Force
- Kink Stability Test
- Simulated Stent Insertion and Removal Test
- Chemical Performance
- Guidewire: Radiopacity, bending test, compatibility with stent and introducer

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusions

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.