March 17, 2022

Ureteral Stent Company
Mike Bunker
CEO
45 Glenridge Court
Chagrin Falls, OH 44022

Re: K213444
Trade/Device Name: RELIEF Ureteral Stent Kit; Model: RS-001 - 6 Fr x 24cm, RELIEF Ureteral Stent Kit; Model: RS-002 - 6 Fr x 26cm
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: February 15, 2022
Received: February 18, 2022

Dear Mike Bunker:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K213444

Device Name

RELIEF Ureteral Stent Kit; Model: RS-001 - 6 Fr x 24cm, RELIEF Ureteral Stent Kit; Model: RS-002 - 6 Fr x 26cm

Indications for Use *(Describe)*

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.

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

1. Submitter Information

510 (k) submitter	Ureteral Stent Company, Inc.
Address	45 Glenridge Court Chagrin Falls, Ohio 44022
Contact Person	Mike Bunker CEO, Ureteral Stent Company Phone: (216) 258 – 8047 Email : mbunker@waldencompanies.com
Preparation date	March 17, 2022

2. Device Name

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
Common Name	Ureteral Stent
Classification Name	Stent, Ureteral
Classification Regulation	21 CFR 876.4620
Device Class	II
Panel	Gastroenterology/Urology
Product Code	FAD

3. Predicate Devices

	Primary Predicate	Secondary Predicate
Owner	Cook Incorporated	Dornier MedTech America Inc.
Trade Name of the Device	Universa® Firm Ureteral Stents and Stent Sets	Dornier CASCADE Ureteral Stent
Classification Name	Stent, Ureteral	Stent, Ureteral
Regulation Classification	21 CFR 876.4620	21 CFR 876.4620
Device Class	II	II
Panel	Gastroenterology/Urology	Gastroenterology/Urology
Product Code	FAD	FAD
510(k) Number	K161236	K190312

4. Device Description

The RELIEF™ Ureteral Stents are sterile, single-use devices. The stents are available in 6Fr, with lengths of 24cm and 26cm. The ureteral stent is constructed of a radiopaque polymer tube with a central lumen with side holes positioned along its length to provide drainage of urine from the kidney to the bladder and includes hydrophilic coating. Along the stent are printed insertion markers throughout its length. The stent includes a radiopaque soft polymeric proximal tubular coil and body segment attached to a 4 cm tether of suture material that is placed along the ureter intramural segment, allowing natural opening, and closing of the ureteral orifice. The tether is attached to a radiopaque distal bladder coil constructed of a monofilament (non-lumened), polymeric segment, allowing it to float in the bladder, thus precluding any tension on the tether or coil. The RELIEF™ Ureteral Stent package contents consist of:

- RELIEF™ Ureteral Stent
- Stent pusher tube with radiopaque tip
- Pigtail straightener

The RELIEF™ Ureteral Stent is not intended as a permanent indwelling device and is labeled for indwell time not to exceed thirty (30) days only). The following models are available for the subject device:

- RS-001: 6Fr x 24cm
- RS-002: 6Fr x 26cm

5. Indications For Use

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.

6. Comparison of the Technological Characteristics with primary Predicate and Secondary Predicate Devices

Device & Predicate Device(s):	K213444	K161236	K190312
General Device Characteristics			
IFU statement	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.	The Dornier CASCADE Ureteral Stent is indicated to relieve obstruction in a variety of benign, malignant and post- traumatic conditions in the ureter such as presence of stones and/or stone fragments, or other ureteral obstructions such as those associated with ureteral stricture, carcinoma 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.
Indwell time	Not to exceed thirty (30) days.	For a 12-month indwell time	Not to exceed 30 days.
Diameter	6 Fr.	4,6,8 Fr.	4.9, 6, 7 and 8 Fr.
Length	24 cm and 26 cm	20, 22, 24, 26, 28 cm lengths	14,20,22,24,26,28 cm Multilength 22-32cm
Distal coil	Distal Coil attached to a distal tether	Distal Coil part of the Ureteral Stent body	Not identified
Bladder coil	3-0 Polypropylene Suture Deklene Maxx	Braided or monofilament tether on proximal pigtail loop	monofilament nylon tether to proximal pigtail loop
Guidewire	6.0 Fr stents accept 0.035” and 0.038” guide wire	6.0 Fr stents accept 0.038” guide wire	4.7 Fr.= .035" diameter; 6, 7/8 Fr.= .038" diameter
Pusher tube	Pusher Tube w/ radiopaque tip	Stent Positioner w/ radiopaque tip	Pusher Tube w/ radiopaque tip
Pigtail straightener?	Yes	Yes	Yes
Sterilization	EtO	EtO	EtO
Single use?	Yes	Yes	Yes

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

7. Performance Data

Below is a list of the tests that have been performed and successfully completed for the subject stents:

- Biocompatibility testing according to ISO 10993-1:2018 - *Biological evaluation of medical devices* — Part 1: Evaluation and testing within a risk management process and FDA Guidance "*Use of International Standard ISO 10993-1*" (2016).

- Ethylene oxide residual testing according to ISO 10993-7:2008 - *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals.*

- EO sterilization according to ISO 11135:2014 - *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.*

The following list 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 to determine the substantial equivalence with the predicates:

- Flow Rate
- Radiopacity
- Tensile Strength
- Elongation
- Dimensional Verification
- Retention Strength
- Tether Junction
- Tensile, Bend Radius and Three Point Bend
- Tensile Strength Radiopaque Tip
- Dynamic Friction
- Guide wire compatibility
- Three Point Bend.

All predetermined acceptance criteria were met.

8. Conclusion

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicates.