March 22, 2024

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

Re: K232920
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: September 15, 2023
Received: September 19, 2023

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 (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.

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 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)*
K232920

Device Name

RELIEF™ Ureteral Stent

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.

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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TRADITIONAL 510(K) SUMMARY

1. SUBMITTER INFORMATION

Applicant	Ureteral Stent Company, Inc. 45 Glenridge Court Chagrin Falls, Ohio 44022
Official Correspondent	Mike Bunker CEO Ureteral Stent Company, Inc. Phone: (216) 258-8047 Email:
Date Prepared	March 19, 2024

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
Product Code:	FAD
Panel:	Gastroenterology/Urology

3. PREDICATE DEVICE IDENTIFICATION

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

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

4. DEVICE DESCRIPTION:

The RELIEF™ Ureteral Stents are sterile, single-use devices. The stents are available in 6Fr, with lengths of 24 cm and 26 cm. 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, thereby preventing vesicoureteral reflux. 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.

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.

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

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

Comparison Element	Subject Device: RELIEF™ Ureteral Stent Kit	Predicate Device: RELIEF™ Ureteral Stent Kit
510(k) Number	**K232920**	**K213444**
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. The stent is not intended as a permanent indwelling device. The indwelling time should not exceed thirty (30) days.	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.
Indwell Time	Not exceed thirty (30) days.	Not exceed thirty (30) days.
Diameter	6 Fr.	6 Fr.
Length	24 cm and 26 cm	24 cm and 26 cm
Distal Coil	Distal Coil attached to a distal tether.	Distal Coil attached to a distal tether.
Bladder Coil	3-0 Polypropylene Suture Deklene Maxx	3-0 Polypropylene Suture Deklene Maxx

Guidewire	6.0 Fr stents accept 0.035" and 0.038" guide wire.	6.0 Fr stents accept 0.035" and 0.038" guide wire.
Pusher Tube	Pusher Tube w/radiopaque tip	Pusher Tube w/radiopaque tip
Pigtail Straightener?	Yes	Yes
Sterilization	EtO	EtO
Single Use?	Yes	Yes

As evidenced by the above table, both the subject and the predicate devices have same design, intended use and technological characteristics. In this 510(k), the sponsor included a new labeling claim that if the subject device is appropriately placed along the ureter intramural segment, it will allow the natural opening and closing of the ureteral orifice, thereby preventing vesicoureteral reflux. This labeling claim was supported by clinical data which are summarized below.

7. SUMMARY OF CLINICAL TESTING:

Clinical data collected from 19 patients were provided to verify that the design of the suture tether does not impede the normal functioning of the urinary orifice to prevent vesicoureteral reflux. This data were obtained from a prospective, open label study called 'Clinical Evaluation of RELIEF ™ Stent study' which was conducted in the University Hospital Cleveland Medical Center. The study enrolled 26 patients who were assessed for eligibility based on the inclusion criteria. Seven patients were excluded based on the exclusion criteria. Total 19 patients were evaluated in the study, including 10 male and 9 female patients. Eleven of the evaluated subjects underwent previous stent placement. Four and 15 of the evaluated patients had renal and ureteral calculi, respectively. The demographics and anatomical height of the subjects, inclusion, and exclusion criteria used for the study are listed below:

Demographics
The patient demographics for the clinical performance testing is referenced below:

Gender	Number of participants	Ethnicity
Male	10	All Caucasian
Female	9	Asian (1) Afro-American (2) Caucasian (6)

The age range for the subjects was 39-84 years.

Anatomical Height criteria:
The patient's anatomical height in relation to the RELIEF™ Ureteral Stent length utilized as referenced below:

Anatomical Height	Stent Length
5' 3" – 5' 7"	24 cm
5' 8" – 5' 10"	26 cm

Inclusion criteria:

1. Male and female patients.
2. Over 18 years of age and willing and able to provide informed consent.
3. Renal or ureteral stone or both calculi between 5-25 mm measured on plain abdomen X-ray Kidney Ureter Bladder (KUB or computed tomography (CT).
4. Upper or middle third ureteral stricture or stone AND/OR stone located in the renal pelvis.
5. Patient agrees to participate in the study and signs the informed consent form.
6. Able to complete self-rated questionnaires.

Exclusion criteria:

1. Patients with distal ureteral obstruction regardless of etiology, patients with known or demonstrated ureteral reflux intraoperatively.
2. Patients with urinary reflux (assessed by pre-stent cystogram).
3. Patients requiring bilateral surgical stone management procedure or patients with active urinary tract infection (UTI) or sepsis.

Study results:
Across the 19 patients evaluated in the study, no patients experienced adverse complications. All cystograms, pre- and post-stent implant, were graded at 'No Reflux'. The comparison of the cystogram images of the RELIEF™ Ureteral Stent verified that the low-profile tether segment of the subject device placed in the intramural segment of the ureter did not impede the urinary orifice's one-way valve function. The normal function of the urinary orifice's one way valve is to close and seal off during micturition, thereby to prevent vesicoureteral reflux.

8. CONCLUSIONS

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