DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 22, 2016

Brightwater Medical
Bob Smouse
CEO/ CMO
816 W. Bennett Ct.
Dunlap, IL 61525

Re: K161277
Trade/Device Name: ConvertX™ Nephroureteral Stent System
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: Class II
Product Code: FAD
Dated: October 13, 2016
Received: October 17, 2016

Dear Bob Smouse,

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Division

Douglas Silverstein -S
2016.11.22 12:05:41 -05'00'

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161277

Device Name

ConvertX Nephroureteral Stent System

Indications for Use *(Describe)*

The ConvertX Nephroureteral Stent System with releasable drainage catheter is delivered percutaneously and is intended to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent, as well as providing external drainage.

For patients for whom external drainage is not, or no longer desirable, the releasable drainage catheter may be removed, leaving the stent to provide internal drainage from the ureteropelvic junction to the bladder.

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.

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with 21 CFR §807.92 the following summary of information is provided:

Submitted By	BrightWater Medical 816 W. Bennett Ct. Dunlap, IL 61525 U.S.A.
Contact Person	Bob Smouse, M.D. Chief Executive Officer / Chief Medical Officer Phone: 1-650-210-8100 Email: bsmouse@brightwatermed.com
Date Prepared	October 13, 2016
Proprietary Name	ConvertX™ Nephroureteral Stent System
Common Name	Ureteral Stent
Classification	Class II
Regulation Number	21 CFR 876.4620
Classification Panel	Gastroenterology/Urology
Product Code	FAD
Predicate Device	K141344, Expel Nephroureteral Stent System with Twist-Loc Hub and Expel Ureteral Stent System
Intended Use / Indications for Use	The ConvertX Nephroureteral Stent System with releasable drainage catheter is delivered percutaneously and is intended to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent, as well as providing external drainage. For patients for whom external drainage is not, or no longer desirable, the releasable drainage catheter may be removed, leaving the stent to provide internal drainage from the ureteropelvic junction to the bladder.

DEVICE DESCRIPTION

The ConvertX Nephroureteral Stent System is a sterile, single-use non-vascular intervention device inserted using percutaneous access techniques to re-establish internal drainage between the ureteropelvic junction and the bladder, and stent the ureter. The ConvertX System allows for external drainage and access as needed.

The ConvertX Nephroureteral Stent System is a single lumen device that has a detachable ureteral stent with proximal and distal pigtails. Both proximal and distal pigtails contain drainage holes. The proximal pigtail forms in the renal pelvis, while the distal pigtail forms in the bladder. The distal pigtail has a tapered, atraumatic tip. Drainage can occur internally (from the ureteropelvic junction to the bladder) or externally (from the ureteropelvic junction to the outside of the patient). A loop suture is attached to the proximal pigtail enabling the pigtail, straightened for delivery, to be closed in the renal pelvis.

The ConvertX Nephroureteral Stent System's Hub has three ports which are used for both ends of the loop suture, external drainage of urine and the ureteral stent release wire. One end of the loop suture and the release wire are connected to pull tabs. The releasable drainage catheter and loop suture may be detached from the ureteral stent when external drainage is no longer necessary, leaving the stent in place. While still attached, the releasable drainage catheter may be used to withdraw the ureteral stent. The ConvertX Nephroureteral Stent System is radiopaque throughout its length.

The ConvertX Nephroureteral Stent System is comprised of the following components:

- Ureteral Stent
- Releasable Drainage Catheter with Hub

The following accessories are provided with the ConvertX Nephroureteral Stent System:

- Metal Stiffening Cannula
- Luer Cap

SUMMARY OF NON-CLINICAL TESTING

Design verification / performance testing for the ConvertX Nephroureteral Stent System was completed in accordance with applicable sections of ASTM F1828-97 - Standard Specification for Ureteral Stents, ASTM F623-99 - Standard Performance Specification for Foley Catheters, ISO 10555-1: 2013 - Intravascular catheters - Sterile and single-use catheters, Part 1: General requirements, and the FDA Guidance for the Content of Premarket Notifications for Ureteral Stents. MRI Compatibility was evaluated according to ASTM F2182-11a - Standard Test Method for Measurement of Radio Frequency Heating On or Near Passive Implants During Magnetic Resonance Imaging, ASTM F2119-07 - Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants, ASTM F2052-15 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment, and ASTM F2503-13 - Standard Practice for Marking Medical Devices and Other Items for Safety in Magnetic Resonance Environment. Radiopacity of the ConvertX

Nephroureteral Stent System was evaluated in accordance with ASTM F640-12 - Standard Test Methods for Determining Radiopacity for Medical Use.

- Stent / Catheter Dimensions
- Stiffener Dimensions
- Straightener to Stent Compatibility
- Guidewire Compatibility
- Loop Recovery
- Flow Recovery Post Kinking
- Stent-Catheter Interface Strength
- Kink Resistance
- Stent Shaft Tensile Strength
- Hub to Shaft Tensile Strength
- Hub to Stiffener Strength
- Stiffener Tip Strength
- Loop Retention / Removal Force
- Pull wire to Pull Tab Tensile Strength
- Loop Suture to Pull Tab Tensile strength
- Frictional Force
- Loop Suture Removal Force
- Lock Suture to Hub Tensile Strength
- Decoupling Force
- Resistance to Deformation
- Urine Compatibility – Stent
- Urine Compatibility –System
- Resistance to Liquid Leakage - Under Pressure and During Aspiration/ Vacuum
- Flow Rate
- Shelf Life
- MRI Compatibility - Conditional
- Sterilization
- Non-pyrogenic - LAL Kinetic Chromogenic
- Biocompatibility
- Radiopacity
- Pouch Seal Strength

The ConvertX Nephroureteral Stent System, including its packaging, met the predetermined acceptance criteria. No new safety or performance issues were raised during testing.

PREDICATE DEVICE COMPARISON

Performance / Technological Characteristic	**Convert X Nephroureteral Stent System**	**Expel Nephroureteral Stent System Twist Loc Hub (K141344)**	**Expel Ureteral Stent System (K141344)**
Indications for Use	The ConvertX Nephroureteral Stent System with releasable drainage catheter is delivered percutaneously and is intended to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent, as well as providing external drainage.	The Expel Nephroureteral Stents are delivered percutaneously and are intended to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent, as well as providing external drainage.	The Expel Ureteral Stent System is delivered percutaneously and is intended to establish drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which does not extend externally.

Performance / Technological Characteristic	Convert X Nephroureteral Stent System	Expel Nephroureteral Stent System Twist Loc Hub (K141344)	Expel Ureteral Stent System (K141344)
	For patients for whom external drainage is not, or no longer desirable, the releasable drainage catheter may be removed, leaving the stent to provide internal drainage from the ureteropelvic junction to the bladder.		
Common Name	Ureteral Stent	Ureteral Stent	Ureteral Stent
Classification	Class II, Performance Standards	Class II, Performance Standards	Class II, Performance Standards
Regulation Number	21 CFR 876.4620	21 CFR 876.4620	21 CFR 876.4620
Product Code	FAD	FAD	FAD
Single Use Only	Yes	Yes	Yes
Provided Sterile	Yes	Yes	Yes
Sterilization Method	EtO	EtO	EtO
Diameters	10.3 French	8.3 and 10.3 French	8.3 and 10.3 French
Stent Lengths	20, 22, 24, 26, 28 cm	22, 24, 26, 28 cm	22, 24, 26, 28 cm
Guidewire Compatibility	0.038”	0.038”	0.038”
Stent Material	Polyurethane	Polyurethane	Polyurethane
Drainage Catheter Material	Polyurethane	Polyurethane	NA
Loop Suture Material	Polyethelyne	Nylon	Nylon
Tapered Stent Tip	Yes	Yes	Yes
Radiopaque	Yes	Yes	Yes
MRI Compatible	Yes	Yes	Yes
Urine Compatible	Yes	Yes	Yes
Maximum Indwelling Time	Not to exceed 30-days	Not to exceed 30-days	Not to exceed 90-days
Delivery Method	Percutaneous	Percutaneous	Percutaneous
Method of conversion from nephroureteral stent to ureteral stent	Disconnect	Removal / Exchange	NA

Performance / Technological Characteristic	Convert X Nephroureteral Stent System	Expel Nephroureteral Stent System Twist Loc Hub (K141344)	Expel Ureteral Stent System (K141344)
Biocompatibility	Meets requirements of 10993-1	Meets requirements of 10993-1	Meets requirements of 10993-1
Accessory Devices	Stiffening Cannula Luer Cap	Cannulas, Plug/Cap, Stabilizer, Pigtail Straightener	Cannulas, Stabilizer, Pigtail Straightener

CONCLUSION

The ConvertX™ Nephroureteral Stent System has the same intended use and similar technological characteristics as the Expel Nephroureteral Stent System with Twist-Loc Hub and Expel Ureteral Stent System (K141344) marketed by Boston Scientific Corporation. Moreover, performance testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the ConvertX Nephroureteral Stent System is substantially equivalent to the predicate devices.