March 14, 2019

BrightWater Medical
Bob Smouse, MD
CEO/CMO
42580 Rio Nedo Road
Temecula, CA 92590

Re: K181669
Trade/Device Name: ConvertX Biliary Stent System
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE
Dated: February 11, 2019
Received: February 12, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter Jr -S

for
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181669

Device Name
ConvertX Biliary Stent System

Indications for Use *(Describe)*
The ConvertX Biliary Stent System with releasable drainage catheter is delivered percutaneously and is intended for internal drainage of the bile ducts, for splinting of the bile ducts during healing, or for providing bile duct patency in a stricture or past a stone 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 bile duct to the duodenum.

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.**

# 510(K) SUMMARY

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

| | |
|---|---|
| **Submitted By** | BrightWater Medical<br>42580 Rio Nedo Rd<br>Temecula, CA 92590<br>U.S.A. |
| **Contact Person** | Bob Smouse, M.D.<br>Chief Executive Officer / Chief Medical Officer<br>Phone: 1-650-210-8100<br>Email: bsmouse@brightwatermed.com |
| **Date Prepared** | June 22, 2018 |
| **Proprietary Name** | ConvertX™ Biliary Stent System |
| **Common Name** | Biliary Stent |
| **Classification** | Class II |
| **Regulation Number** | 21 CFR 876.5010 |
| **Regulation Name** | Biliary catheter and accessories |
| **Classification Panel** | Gastroenterology/Urology |
| **Product Code** | FGE |
| **Predicate Devices** | Boston Scientific Advanix™ Double Pigtail (K101786), Boston Scientific Expel™ Drainage Catheter (K141335) |
| **Reference Device** | BrightWater Medical ConvertX Nephroureteral Stent System (K161277) |
| **Intended Use / Indications for Use** | The ConvertX Biliary Stent System with releasable drainage catheter is delivered percutaneously and is intended for internal drainage of the bile ducts, for splinting of the bile ducts during healing, or for providing bile duct patency in a stricture or past a stone 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 bile duct to the duodenum. |

**Device Description**

The ConvertX Biliary Stent System is a sterile, single-use non-vascular interventional device inserted using percutaneous access techniques to re-establish internal drainage and is intended for internal drainage of the bile ducts, for splinting of the bile ducts during healing, or for providing bile duct patency in a stricture or past a stone. The ConvertX Biliary System allows for external drainage and access as needed.

The ConvertX Biliary Stent System has two primary components: a double pigtail Biliary Stent and a Releasable Drainage Catheter with Hub.

The ConvertX Biliary Stent System is a single lumen device that has a detachable Biliary Stent with proximal and distal loops (pigtails). Both proximal and distal loops (pigtails) contain drainage holes. The proximal pigtail forms in the bile duct, while the distal pigtail forms in the duodenum. The distal pigtail has a tapered, atraumatic tip. Drainage can occur internally (from the bile duct to the duodenum) or externally (from the bile duct to the outside of the patient). A suture ("Loop Suture") is threaded through the proximal pigtail enabling the pigtail, straightened for delivery, to be closed in the bile duct.

The ConvertX Biliary Stent System's Hub has three ports which are used for both ends of the Loop Suture, external drainage of bile and the release wire. Ends of the Loop Suture and the Release Wire are connected to separate pull tabs within the Hub. The Releasable Drainage Catheter and Loop Suture may be detached from the Biliary 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 Biliary Stent. The ConvertX Biliary Stent System is radiopaque throughout its length and has a marker on the stent between junction and proximal loop

The ConvertX Biliary Stent System is comprised of the following functional components:

- Biliary Stent
- Releasable Drainage Catheter with Hub

The ConvertX Biliary Stent System is supplied with the following accessories:

- Metal Stiffening Cannula
- Luer Cap
- Plastic Stiffening Cannula
- Loop Straightener

**Summary of Non-Clinical Testing**

Design verification / performance testing for the ConvertX Biliary Stent System was completed in accordance with applicable sections of ASTM F1828-97 - *Standard Specification for Ureteral Stents (using simulated bile),* ASTM F2129-17– *"Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices"*: X2.5 Simulated Bile (Human Simulated Bile).

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. Biological testing was performed in accordance with applicable sections of ISO 10993 – *Biological Evaluation of Medical Devices*. 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 predicate 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
- Bile Compatibility – Stent
- Bile Compatibility- System
- Resistance to Liquid Leakage - Under Pressure and During Aspiration/ Vacuum
- Flow Rate
- Shelf Life
- MRI Compatibility - Conditional
- Sterilization
- Biocompatibility
- Radiopacity
- Pouch Seal Strength
- Corrosion Testing
- Simulated Use Testing

The ConvertX Biliary 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 Biliary Stent System Submitted** | **Boston Scientific Advanix™ Double Pigtail K101786** | **Boston Scientific Expel Drainage Catheter K141335** | **ConvertX Nephroureteral Stent System K161277 (Reference Device)** |
|---|---|---|---|---|
| Indications for Use | The ConvertX Biliary Stent System with | Advanix Double Pigtail Biliary | The drainage catheter is intended | The ConvertX Nephroureteral Stent |

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|---|---|---|---|---|
| | releasable drainage catheter is delivered percutaneously and is intended for internal drainage of bile ducts, for splinting of the bile ducts during healing, or for providing bile duct patency in a stricture or past a stone while maintaining external access to the stent, as well as providing external drainage.<br><br>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 bile duct to the duodenum | Stent is intended for drainage of the bile ducts, for splinting of a bile duct during healing, or for providing bile duct patency in a stricture or past a stone. | to provide percutaneous drainage of abscess fluid and biliary collections | 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.<br><br>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 | Biliary Stent | Biliary Stent | Biliary Catheter | Ureteral Stent |
| Classification | Class II, Performance Standards | Class II, Performance Standards | Class II, Performance Standards | Class II, Performance Standards |
| Regulation Number | 21 CFR 876.5010 | 21 CFR 876.5010 | 21 CFR 876.5010 | 21 CFR 876.5010 |
| Product Code | FGE | FGE | FGE | FAD |
| Single Use Only | Yes | Yes | Yes | Yes |
| Provided Sterile | Yes | Yes | Yes | Yes |
| Sterilization Method | EtO | EtO | EtO | EtO |
| Diameters | 10.3 F | 7, 8.5 & 10F | 8F to 14F | 10.3F |
| Stent Lengths | 5,7,10, and 15 cm | 3 cm to 15 cm | 20 to 40 cm | 20 to 28 cm |
| Guidewire Compatibility | 0.038” | 0.038” | 0.038” | 0.038” |
| Stent Material | Polyurethane | Styrene Butadiene Styrene | Polyurethane | Polyurethane |
| Drainage Catheter Material | Polyurethane | Polyurethane | Polyurethane | Polyurethane |
| Loop Suture Material | Polyethylene | Nylon | Nylon | Polyethylene |
| Tapered Stent Tip | Yes | Yes | Yes | Yes |

| | | | | |
|---|---|---|---|---|
| Radiopaque | Yes | Yes | Yes | Yes |
| MRI Compatible | Yes | Yes | Yes | Yes |
| Bile Compatible | Yes | Yes | Yes | Yes |
| Maximum Indwelling Time | Catheter: Not to exceed 30-days<br>Stent: Not to exceed 90-days | Not to exceed 90-days | Not to exceed 90-days | Not to exceed 30-days |
| Delivery Method | Percutaneous | Percutaneous | Percutaneous | Percutaneous |
| Method of conversion to stent | Disconnect | N/A | N/A | Disconnect |
| Biocompatibility | Meets requirements of 10993-1 | Meets requirements of 10993-1 | Meets requirements of 10993-1 | Meets requirements of 10993-1 |
| Accessory Devices | Metal Stiffening Cannula<br>Plastic Stiffening Cannula<br>Loop Straightener<br>Luer Cap | NaviFlex™ RX Delivery System | Cannulas<br>Trocars<br>Connecting Tubes<br>Plugs / Caps<br>Pigtail Straightener<br>Facial Dilators<br>Guidewires<br>Dressing<br>Catheter Cuff<br>Introducers | Stiffening Cannula<br>Luer Cap |

## Conclusion

The ConvertX™ Biliary Stent System has the same intended use and similar technological characteristics as the Advanix Double Pigtail Stent System and Expel Drainage Catheter marketed by Boston Scientific. 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 Biliary Stent System is substantially equivalent to the predicate devices.