November 15, 2019

Dornier MedTech America Inc.
John Hoffer
Vice President Quality, Regulatory, Clinical
1155 Roberts Blvd, Suite 100
Kennesaw, GA 30144

Re: K190312
Trade/Device Name: Dornier CASCADE Ureteral Stent
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: FAD
Dated: October 7, 2019
Received: October 7, 2019

Dear John Hoffer:

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,

Sharon M. Andrews
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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K190312

Device Name

Dornier CASCADE Ureteral Stent

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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 – K190321

Dornier CASCADE Ureteral Stent

Submitter Name and Address
Dornier MedTech America,
Inc. 1155 Roberts Blvd.
Kennesaw, GA 30144

Date Prepared
October 7, 2019

Contact Person
John Hoffer
Phone: 770-514-6163

Name/Address of Sponsor
Dornier MedTech America,
Inc. 1155 Roberts Blvd.
Kennesaw, GA 30144

Device Information

Name of Device:	Dornier CASCADE Ureteral Stent
Common or Usual Name:	Ureteral stent
Classification Name:	Ureteral stent
Classification:	21 CFR 876.4620
Class	II
Product Code:	FAD

Predicate Device
Bard Inlay Stent (K983498)
The predicate device has not been subject to a design related recall.

Device Description

The Dornier CASCADE Ureteral Stents are sterile, single-use devices. The stents are available in 4.9 to 8.0 French (Fr) diameter, with lengths ranging from 14.0 to 32.0 centimeters (cm). The stents are constructed of a thermoplastic polyurethane elastomer. The base polyurethane material is compounded with $BaSO_4$ to render the stent radiopaque under x-ray fluoroscopy.

Drainage holes extend along the body of the stent as well as on the pigtails to provide drainage. The stents are secured in the urinary tract with pigtail loops on the proximal and distal ends. A monofilament tether for repositioning and removal of the device is located on the proximal pigtail (bladder end) of the stent. Along the stent are graduation marks to provide visualization during stent advancement and placement. The CASCADE Ureteral Stent includes a pigtail straightener, a small polymer tube to aid in placement over a wire guide. The pigtail straightener is removed prior to use. The CASCADE Ureteral Stents are labeled for a maximum 30-day indwell time.

The stents are packaged into a pre-formed tray and sealed within a Tyvek pouch. The individually sealed Tyvek pouches are labeled with identification labeling and then packaged into a corrugated shipping box. The packaged stents are sterilized by a contract sterilizer using ethylene oxide.

Indications for Use Statement

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.

Substantial Equivalence

The subject and predicate device have the same indications for use statement.

The subject and predicate device have different technological characteristics including minor differences in design and dimension and a change in indwelling time (maximum of 30 days for the subject device vs maximum of 365 days for the predicate device. These differences in technological characteristics do not raise different questions of safety or effectiveness.

Performance Data

The CASCADE Ureteral Stent was subjected to the following tests to assure design and performance under the specified testing parameters:

- Sterilization validation
- Shelf life, including packaging validation and functional performance testing
- Biocompatibility
    - Stent: cytotoxicity, skin sensitization, skin irritation, acute systemic toxicity, material-mediated pyrogenicity, genotoxicity (Ames bacterial reverse mutation, in vitro mouse lymphoma assay), and implantation studies (2-week, muscular), 13-weeks subcutaneous implantation, and chemical characterization followed by the risk assessment of extractables with the stent
    - Pusher: cytotoxicity, skin sensitization, skin irritation, acute systemic toxicity and material-mediated pyrogenicity
- Bench Performance Testing, including visual inspection, dimensional analysis, pigtail retention, suture retention, coefficient of friction, tensile strength, elongation, radiopacity, and flow rate.

The performance and functional testing are based on the FDA guidance "Guidance for the Content of Premarket Notifications for Ureteral Stents" and the ASTM F1828-17, "Standard Specifications for Ureteral Stents." All testing was found to be acceptable and bench performance testing comparable to the

predicate device.

Conclusion

The Dornier CASCADE Ureteral Stent is substantially equivalent to its predicate device.