September 18, 2019

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

Re: K191187
Trade/Device Name: Dornier MINNOW Ureteral Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EYB
Dated: July 17, 2019
Received: July 19, 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
Acting 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)*

K191187

Device Name

Dornier MINNOW Ureteral Catheter

Indications for Use *(Describe)*

The Dornier MINNOW Ureteral catheter is indicated for access and catheterization of the urinary tract, including the following applications:
Delivery of contrast media
Drainage of fluids from the urinary tract
Delivery of irrigation fluids to the urinary tract
Navigation of a tortuous ureter
Access, advancement, or exchange of wire guides

The target population is for adults only (at least 22 years old).

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)*

510(k) SUMMARY

Dornier MINNOW Ureteral Catheter

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Dornier MedTech America, Inc.
1155 Roberts Blvd., Suite 100
Kennesaw, GA 30144

Date Prepared: 4/30/19

Contact Person: John Hoffer Phone: 770-514- 6163
Name/Address of Sponsor and Name of Device

Dornier MedTech America, Inc.
1155 Roberts Blvd.
Kennesaw, GA 30144

Device Name –	Dornier MINNOW Ureteral Catheter 5F x 70cm Open Tip Ureteral Catheter - MIOTO570R 6F x 70cm Open Tip Ureteral Catheter - MIOTO670L
Common Name -	Ureteral Catheter
Classification Number -	876.1530
Classification Name -	Urological catheter and accessories
Product Code -	EYB
Product Code Name -	Catheter, ureteral, gastro-urology [GU]
Regulatory Class -	II

Predicate Device
Cook Open End Ureteral Catheter (K171662).

Purpose of the 510(k) Notice
The purpose of this submission is to obtain marketing clearance for the Dornier MINNOW Ureteral Catheter product line.

Intended Use/Indications for Use
The Dornier MINNOW Ureteral catheter is indicated for access and catheterization of the urinary tract, including the following applications:

Delivery of contrast media
Drainage of fluids from the urinary tract Delivery of irrigation fluids to the urinary tract Navigation of a tortuous ureter
Access, advancement, or exchange of wire guides

The target population is for adults only (at least 22 years old).

Device Description

The MINNOW Ureteral Catheter is a sterile single use, single lumen medical grade thermoplastic elastomer (Pebax®) catheter. It is designed to assist in access to the upper urinary tract using standard endoscopic technique for drainage and delivery of gels or fluids. The device is offered without side holes and is available in 5 and 6 Fr. Sizes, which are common to the industry. The catheter is indicated for use by physicians for facilitating access to the urinary tract through a retrograde route and may be used in conjunction with a guidewire or for the injection of gels or fluids into the urinary tract. The catheter tip is radiused and has a .041" ID that allows for a smooth transition and passage when placed over a guidewire of up to 0.038" inches in diameter that is pre-positioned through the urological tract. The MINNOW Ureteral Catheters are packaged with a standard Touhy-Borst adapter that allows for injection or aspiration of fluids, but removable to allow for scope exchange without having to remove the catheter. The MINNOW Ureteral Catheters are available in 5 and 6 French (Fr) diameter, with a catheter length of 70 centimeters (cm). Dimensional details are below.

Catheter Size	OD	ID	Tip ID	Length
5FR	.065" +/- .002"	.041" +/-.002"	.041" +/- .001"	70cm +/- 2cm
6FR	.078" +/- .002"	.049" +/- .002"	.041" +/- .001"	70cm +/- 2cm

The MINNOW Ureteral Catheters are constructed of a medical grade thermoplastic elastomer (Pebax®). This material has been USP Class VI tested and has passed all applicable biocompatibility testing. The base material is compounded with BaSO4 to render the MINNOW Ureteral Catheter radiopaque under x-ray fluoroscopy. All material colorants used are compliant with FDA standards.

Technological Characteristics

The basic characteristics of the Dornier MINNOW Ureteral Catheter are substantially equivalent to the predicate device. They are both made from medical grade material and are a single lumen design with an open tip. Both are radiopaque and can be visualized under fluoroscopy. They are able to be passed over a 0.038 guidewire during clinical use.

Performance Data

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

- Sterility
- Packaging
- Biocompatibility
- Radiopacity
- Effective Working Length
- Catheter Shaft ID
- Catheter Tensile Strength
- Catheter Stiffness

All testing was found to be acceptable and substantially equivalent to those of the predicate device.

Substantial Equivalence

A comparison of design characteristics has been performed and demonstrates that the proposed MINNOW Ureteral Catheter is substantially equivalent to the predicate device in terms of intended use, technological characteristics, type of materials and performance characteristics. Therefore, the proposed MINNOW Ureteral Catheter is as safe, as effective, and performs as well as the predicate device.

Conclusion

Based on the data and information comparing the MINNOW Ureteral Catheter and the predicate device we conclude they are substantially equivalent as they have the same intended use, basic design, principle of operation, technology, materials, and performance to the predicate. Any minor differences between the subject and predicate devices do not raise any concerns regarding the overall safety or effectiveness. Thus, the MINNOW Ureteral Catheter is substantially equivalent to its predicate device.