December 6, 2019

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

Re: K190612
Trade/Device Name: EQUINOX Balloon Dilatation Catheter
Regulation Number: 21 CFR 876.5470
Regulation Name: Ureteral dilator
Regulatory Class: II
Product Code: EZN, KOE
Dated: October 22, 2019
Received: October 22, 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,

Jessica K. Nguyen, Ph.D.
Acting 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)*

K190612

Device Name

Dornier EQUINOX Balloon Dilatation Catheter

Indications for Use *(Describe)*

The Dornier EQUINOX Balloon Dilatation Catheter is indicated for dilation of the urinary tract.

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.

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510(k) SUMMARY
Dornier EQUINOX Balloon Dilatation Catheter

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

Dornier MedTech America, Inc.
1155 Roberts Blvd., Suite 00
Kennesaw, GA 30144

Date Prepared: October 18, 2019

Contact Person: John Hoffer

Phone: 770-514- 6163

Name of Device and Name/Address of Sponsor

Dornier EQUINOX Balloon Dilatation Catheter

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

Common or Usual Name

Ureteral Balloon Dilatation Catheter

Classification Name

According to 21 C.F.R. § 876.5470, the Food and Drug Administration ("FDA" or "the agency") has classified Ureteral Dilators as Class II devices (performance standards). The Product Code for these Dilators is EZN.

Predicate Device

Boston Scientific's Uromax Ultra Balloon Dilatation Catheter (K130804)

Purpose of the 510(k) Notice

The purpose of this submission is to obtain marketing clearance for the Dornier EQUINOX Balloon Dilatation Catheter product line.

Intended Use/Indications for Use

The Dornier EQUINOX Balloon Dilatation Catheter is indicated for dilation of the urinary tract.

Device Description

The Dornier EQUINOX Balloon Dilatation Catheter is a multiple lumen catheter with a dilatation balloon mounted at the distal tip. Dilatation balloon catheters are used to exert radial force to dilate narrow ureteral segments.
The Dornier EQUINOX Balloon Dilatation Catheters are sterile, single-use devices. The EQUINOX Balloon Dilatation Catheters are available in 5.8 French (Fr) diameter, with a catheter length of 80 centimeters (cm). There will be three (3) balloon diameters, (4mm, 5mm and 6mm) and two (2) balloon lengths (4cm and 10cm)

The Dornier EQUINOX Balloon Dilatation Catheters are constructed of a medical grade nylon material. This material has been USP Class VI tested. The base material is compounded with BaSO4 to render the Dornier EQUINOX Balloon Dilatation Catheter radiopaque under x-ray fluoroscopy. The catheter also has radio-opaque marker bands on the proximal and distal ends of the balloon for visualization during use. All colorants used are compliant with FDA standards.

Technological Characteristics

The Dornier EQUINOX Balloon Dilatation Catheters have the same basic technological characteristics as the predicate device, Boston Scientific's Uromax Ultra Balloon Dilatation Catheter. They both are a multiple lumen catheter with a dilatation balloon mounted at the distal tip. They are both manufactured using PET for the inflation balloon which is the primary functional component of the devices. At the proximal end, they both have leur lock connectors that will attach to the inflation device to inflate the balloon during use. As noted above, both devices are compounded with Barium sulfate and radiopaque marking bands to allow visualization under fluoroscopy.

Performance Data

The Dornier EQUINOX Balloon Dilatation Catheter was subjected to the following tests to assure design and performance under the specified testing parameters:

Sterility
Packaging
Biocompatibility
Balloon Burst
Durability Test
Balloon Deflation Time
Balloon/Scope Compatibility
Radiopacity
Effective Working Length
Catheter Tip Length Balloon
Diameter @ RBP Balloon
Length @ OP Catheter Shaft OD

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 Dornier EQUINOX Balloon Dilatation Catheter is substantially equivalent to the predicate device in terms of intended use, technological characteristics, type of materials and performance characteristics. Therefore, the proposed Dornier EQUINOX Balloon Dilatation Catheter is as safe, as effective, and performs as well as the predicate device.

Conclusion

Based on the data and information comparing the Dornier EQUINOX Balloon Dilatation 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 Dornier EQUINOX Balloon Dilatation Catheter is substantially equivalent to its predicate device.