November 20, 2020

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

Re: K201815
Trade/Device Name: Dornier MAGELLAN Ureteral Access Sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: II
Product Code: FED
Dated: October 21, 2020
Received: October 22, 2020

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,

Mark J. Antonino, M.S.
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)*

K201815

Device Name

**Dornier MAGELLAN Ureteral Access Sheath**

Indications for Use *(Describe)*

The Dornier MAGELLAN Ureteral Access Sheath is indicated for use in endoscopic urology procedures where ureteral dilation and ureteral access is desired for injection of fluids and insertion and removal of endoscopes and related instruments.

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)*

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**

**Dornier MAGELLAN Ureteral Access Sheath**

**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: 06/08/2020

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

| | |
|---|---|
| Trade Name: | Dornier MAGELLAN Ureteral Access Sheath |
| Common Name: | Ureteral Access Sheath |
| Classification Name: | Endoscopic Overtube |
| Regulation: | 21 CFR §876.1500 |
| Regulatory Classification: | II |
| Product Code**:** | FED |

Predicate Device

C.R. Bard Proxis™ Ureteral Access Sheath (K160861)

Purpose of the 510(k) Notice

The purpose of this submission is to obtain marketing clearance for the Dornier MAGELLAN Ureteral Access Sheath product line.

Intended Use/Indications for Use

The Dornier MAGELLAN Ureteral Access Sheath is indicated for use in endoscopic urology procedures where ureteral dilation and ureteral access is desired for injection of fluids and insertion and removal of endoscopes and related instruments. The target population is for adults only (at least 22 years old).

Device Description

The Dornier MAGELLAN Ureteral Access Sheath is a two component ureteral dilatation system that provides an open conduit to the upper urinary tract to facilitate Ureteroscopy, which contains a single lumen for injection of fluids as well as passage of endoscopes and related instruments. The packaged product includes a Hydrophilic-coated Dilator with a locking mechanism and a Hydrophilic-coated sheath with hub. The Access Sheath is a sterile, single use, disposable device that allows access to the ureter to facilitate scope and urological tool passage.

The Dornier MAGELLAN Ureteral Access Sheaths are constructed of a medical grade thermoplastic elastomer (Pebax®). This material has been USP Class VI tested. All colorants used are compliant with FDA standards.

Technological Characteristics

The Dornier MAGELLAN Ureteral Access Sheath has similar technological characteristics as the predicate device, The Proxis™ Ureteral Access Sheath. The subject and predicate devices are based on the following technological elements:

- Similar indications for use
- Similar design features
- Provided sterile for single-use
- Composed of biocompatible materials

The basic characteristics of the Dornier Dornier MAGELLAN Ureteral Access Sheath are substantially equivalent to the predicate device. They are both made from medical grade material and are a single lumen design with a Hydrophilic-coated sheath with hub pen tip.

Performance Data

The Dornier MAGELLAN Ureteral Access Sheath was subjected to the following tests to assure design and performance under the specified testing parameters:

Sterility
Packaging
Biocompatibility
Radiopacity
Sheath ID
Dilator OD
Sheath Distal Tip ID
Dilator Taper length
Kink Resistance
Assembly Flexibility-3 point bend test
Sheath/Hub Tensile
Dilator /Hub Tensile

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 MAGELLAN Ureteral Access Sheath is substantially equivalent to the predicate device in terms of intended use, technological characteristics, type of materials and performance characteristics. Therefore, the proposed Dornier MAGELLAN Ureteral Access Sheath is as safe, as effective, and performs as well as the predicate device.

Conclusion

Based on the data and information comparing the Dornier MAGELLAN Ureteral Access Sheath 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 MAGELLAN Ureteral Access Sheath is substantially equivalent to its predicate device.