May 19, 2021

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

Re: K210394
Trade/Device Name: Dornier Bipolar Cable
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FAS
Dated: April 15, 2021
Received: April 16, 2021

Dear John S. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210394

Device Name

Dornier Bipolar Cable

Indications for Use *(Describe)*

The Dornier Bipolar Cable is indicated to be used with a compatible electrosurgical generator and an HF electrode for endoscopic treatment in urological applications: Cutting, ablation, resection, vaporization and coagulation with HF current

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Dornier Bipolar Cable

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: 02/05/2021

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 Bipolar Cable
Common Name:	Electrosurgical accessory
Classification Name:	Endoscopic electrosurgical unit and accessories.
Regulation Number:	21 CFR 876.4300
Regulatory Class:	II
Product Code:	FAS

Predicate Device

Olympus Resection Electrodes with HF cable (K171965)

Purpose of the 510(k) Notice

The purpose of this submission is to obtain marketing clearance for the Dornier Bipolar Cable product line.

Intended Use/Indications for Use

The Dornier Bipolar Cable is indicated to be used with a compatible electrosurgical generator and an HF electrode for endoscopic treatment in urological applications: Cutting, ablation, resection, vaporization and coagulation with HF current.

Device Description

The Dornier Bipolar Cable is a sterile, single use, disposable device that allows connection of an electrosurgical generator to an HF electrosurgical resection and vaporization electrode. The outer body of the Dornier Bipolar Cables are constructed of a medical grade thermoplastic elastomer. The cable consists of a double wire zip cord with one plug end which has four (4) banana and one (1) straight pin, style of connector that is then attached to the generator. The other end is separated and has two (2) overmolded connectors, one male pin on a wire and one female pin on a wire which are compatible with the HF Electrode.

Technological Characteristics

The Dornier Bipolar Cable has similar technological characteristics as the predicate device, The Olympus Resection Electrodes with HF cable (K171965). It should be noted that this submission is for the connection cable only and does not contain an electrode. The subject and predicate cable device are based on the following technological elements:

- Similar indications for use
- Similar design features
- Similar technological features
- Provided sterile for single-use

The basic characteristics of the Dornier Bipolar Cable are substantially equivalent to the cable included within the predicate device submission.

Performance Data

The Dornier Bipolar Cable was subjected to the following tests to assure design and performance under the specified testing parameters:

Sterility
Packaging
Biocompatibility
Electrical Safety Testing
IEC 60601-1-2:2014
Testing limited to Radiated Emissions (EN 55011)
Radiated and Conducted Immunity (EN 61000-4-3 and EN 61000-4-6)

ANSI/AAMI/IEC 60601-2-2: 2009
201.8.8.3.102 ACTIVE ACCESSORY HF leakage,
201.8.8.3.103 ACTIVE ACCESSORY HF dielectric strength,
201.8.8.3.104 ACTIVE ACCESSORY mains frequency dielectric strength

Dimensional Tests
Connector grip test
Continuity test
Cable insulation HF and Mains Dielectric Strength test
Cable tensile strength tests
Activation recognition and operation
Insulation Resistance
Endurance Test
Connector pull force
Surface temperature measurement test

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

Conclusion

Based on the data and information comparing the Dornier Bipolar Cable 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 device do not raise any concerns regarding the overall safety or effectiveness. Thus, the Dornier Bipolar Cable is substantially equivalent to its predicate device.