November 21, 2025

Dornier MedTech America Inc (DMTA)
John Hoffer
Vice President Quality/Regulatory
1155 Roberts Blvd
Suite 100
Kennesaw, Georgia 30144

Re: K251403
Trade/Device Name: Dornier Bi-Polar Electrode BIP12CLM Bipolar 12 Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIP12CLL Bipolar 12 Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIP30CLM Bipolar 30 Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIP30CLL Bipolar 30 Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIPMBLA Bipolar Medium Bladder Loop 24 Fr Electrode-Sterile, Single-Use BIPNEEL Bipolar Needle 24 Fr Electrode-Sterile, Single-Use BIPDDSC Bipolar Disc)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and accessories
Regulatory Class: II
Product Code: FAS
Dated: October 30, 2025
Received: October 31, 2025

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 (the 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 available 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: The Center for Devices and Radiological Health (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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Mark J. Antonino, M.S.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251403

Device Name

Dornier Bi-Polar Electrode
BIP12CLM Bipolar 12° Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIP12CLL Bipolar 12° Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIP30CLM Bipolar 30° Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIP30CLL Bipolar 30° Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIPMBLA Bipolar Medium Bladder Loop 24 Fr Electrode-Sterile, Single-Use
BIPNEEL Bipolar Needle 24 Fr Electrode-Sterile, Single-Use
BIPDDSC Bipolar Disc

Indications for Use *(Describe)*

INDICATIONS FOR USE AS A RESECTION ELECTRODE:
The Dornier Bi Polar Electrode is designed and intended for use in endoscopic urological surgical procedures involving the resection, ablation, or removal of soft tissue and where hemostasis is required. The specific urological indications include use in the prostate, bladder and bladder neck. The procedure for which the devices can be used are: Transurethral resection in saline (TURis), Transurethral prostatectomy, transurethral resection of the prostate (TURP), for benign prostatic hyperplasia, Transurethral incision of the prostate (TUIP) or bladder neck, Transurethral resection of bladder tumors (TURBT) and cystodiathermy. These devices are intended to be used in an irrigated environment. These devices are not intended to be used in treating cancer of the prostate.

The following electrodes are intended to be used as resection electrodes:
BIP12CLL: BIPOLAR 12° Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIP12CLM: BIPOLAR 12° Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIP30CLL: BIPOLAR 30° Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIP30CLM: BIPOLAR 30° Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIPMBLA: BIPOLAR Medium Bladder Loop 24 Fr Electrode-Sterile, Single-Use
BIPNEEL: BIPOLAR Needle 24 Fr Electrode-Sterile, Single-Use

INDICATIONS FOR USE AS A VAPORIZATION ELECTRODE:
The Dornier Bi Polar Electrode is designed and intended for use in urological surgical procedures involving vaporization, ablation, coagulation, cutting, removal of soft tissue and coagulation where hemostasis is required. The specific soft tissue indication include: Use in the prostate, bladder, and bladder neck. The specific treatment indications include benign prostate hyperplasia (BPH), bladder cancer, tumors, lesions and neoplasms. The specific urological indications include Transurethal Electro vaporization (TUVP), (TVP), (TUEVP) also known as Transurethal Vapor Resection of the prostate (TUVRP), Transurethal Vaporization in Saline (TUVis). These devices are intended to be used in an irrigated environment. These devices are not intended to be used in treating cancer of the prostate.

The following electrode is intended to be used for plasma vaporization:
BIPDDSC: BIPOLAR Dornier DiscTM 24 Fr Electrode-Sterile, Single-Use

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) #: K251403

510(k) Summary

Prepared on: 2025-11-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dornier MedTech America Inc (DMTA)
Applicant Address	1155 Roberts Blvd, Suite 100 Kennesaw GA 30144 United States
Applicant Contact Telephone	7705146163
Applicant Contact	Mr. John Hoffer
Applicant Contact Email	jhoffer@dornier.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Dornier Bi-Polar Electrode (BIP12CLM Bipolar 12° Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIP12CLL Bipolar 12° Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIP30CLM Bipolar 30° Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIP30CLL Bipolar 30° Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIPMBLA Bipolar Medium Bladder Loop 24 Fr Electrode-Sterile, Single-Use BIPNEEL Bipolar Needle 24 Fr Electrode-Sterile, Single-Use BIPDDSC Bipolar Disc
Common Name	Bi Polar Electrode
Classification Name	Electrode, Electrosurgical, Active, Urological
Regulation Number	876.4300
Product Code(s)	FAS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K151976	Omnitech HF Resection/Vaporization Electrode	FAS

Device Description Summary

21 CFR 807.92(a)(4)

The Dornier Bipolar electrodes are sterile packaged, bipolar electrodes designed to deliver high frequency electrosurgical energy at the treatment area of the patient. Dornier bipolar electrodes are intended for single-use only.

The electrodes are designed to be connected through a compatible resectoscope to the electrosurgical unit for the delivery of electrosurgical energy at the treatment area of the patient. It is suitable for surgical cutting, coagulation and removal of soft tissues by controlled heating effect.

The Dornier Bipolar Electrode shall be used in conjunction with compatible resectoscopes such as Olympus Bipolar 12° and Olympus Bipolar 30° to the compatible bipolar electrosurgical generator such as Gyrus PlasmaKineticTM SuperPulse Generator and Olympus ESG

400.
Electrical energy is supplied by the generator. A cable is connected from the generator to the working element of the Resectoscope. The Positive lead attaches to the bottom of the working element and the negative to the top of the working element. Electrical current flows from the generator into the Connector, down the Inner Tube and into the tip of the probe, creating a plasma field. The current returns via the saline, through Forks and Scope, into the negative lead and back to the generator. The strength of the plasma field can be adjusted by increasing or lowering the power setting on the generator. A foot switch is used to turn the electrode on and off.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

INDICATIONS FOR USE AS A RESECTION ELECTRODE:
The Dornier Bi Polar Electrode is designed and intended for use in endoscopic urological surgical procedures involving the resection, ablation, or removal of soft tissue and where hemostasis is required. The specific urological indications include use in the prostate, bladder and bladder neck. The procedure for which the devices can be used are: Transurethral resection in saline (TURis), Transurethral prostatectomy, transurethral resection of the prostate (TURP), for benign prostatic hyperplasia, Transurethral incision of the prostate (TUIP) or bladder neck, Transurethral resection of bladder tumors (TURBT) and cystodiathermy. These devices are intended to be used in an irrigated environment. These devices are not intended to be used in treating cancer of the prostate.

The following electrodes are intended to be used as resection electrodes:
BIP12CLL: BIPOLAR 12° Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIP12CLM: BIPOLAR 12° Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIP30CLL: BIPOLAR 30° Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIP30CLM: BIPOLAR 30° Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use
BIPMBLA: BIPOLAR Medium Bladder Loop 24 Fr Electrode-Sterile, Single-Use
BIPNEEL: BIPOLAR Needle 24 Fr Electrode-Sterile, Single-Use

INDICATIONS FOR USE AS A VAPORIZATION ELECTRODE:
The Dornier Bi Polar Electrode is designed and intended for use in urological surgical procedures involving vaporization, ablation, coagulation, cutting, removal of soft tissue and coagulation where hemostasis is required. The specific soft tissue indication include: Use in the prostate, bladder, and bladder neck. The specific treatment indications include benign prostate hyperplasia (BPH), bladder cancer, tumors, lesions and neoplasms. The specific urological indications include Transurethal Electro vaporization (TUVP), (TVP), (TUEVP) also known as Transurethal Vapor Resection of the prostate (TUVRP), Transurethal Vaporization in Saline (TUVis). These devices are intended to be used in an irrigated environment. These devices are not intended to be used in treating cancer of the prostate.

The following electrode is intended to be used for plasma vaporization:
BIPDDSC: BIPOLAR Dornier DiscTM 24 Fr Electrode-Sterile, Single-Use

Indications for Use Comparison 21 CFR 807.92(a)(5)

The predicate device and the device subject to this submission have the same indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The Dornier Bi Polar Electrode has essentially the same technological characteristics as the predicate device. Both devices are comparable in their design, their mechanical characteristics and their use. As noted above, the indication for use are the same for both devices. The devices are both single use and are sterilized with ETO. The only significant difference between the products is the use of tungsten versus platinum/irridium to form the loop and needle cutting surfaces.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following performance bench testing was conducted to verify that the performance of the Dornier Bi-Polar Electrode is substantially equivalent to the predicate device, and that the device will perform as intended.

General performance testing including:
- Dimensional Analysis
- Mechanical Characteristics - Tensile Strengths

Thermal penetration Testing
Electrical Safety Testing
IEC 60601-1-2:2014
IEC 60601-1
Simulated Use Testing

Testing data and results demonstrate that the Dornier Bi Polar Electrode meets all the pre-determined testing and acceptance criteria.

The following Biocompatibility testing was performed:

Cytotoxicity as per ISO 10993-5:2009
Irritation as per ISO 10993-23:2021
Sensitization as per ISO 10993-10:2021
Pyrogen Testing as per ISO 10993-11:2017
Systemic Toxicity Testing as per ISO 10993-11

Biocompatibility testing demonstrate that the device components that are in contact with the patient are biocompatible.

Sterilization by ethylene oxide has been validated for Dornier Bi Polar Electrode in accordance with EN ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

The nonclinical performance bench testing of the device demonstrates the Dornier Bi Polar Electrode meets its design requirements. The testing also shows the subject device is substantially equivalent in these characteristics to the predicate device.

No clinical testing was used to support substantial equivalence to the predicate device.

Based on the non clinical bench testing, we have concluded the Dornier Bi-Polar Electrode is as safe, as effective, and performs as well as the legally marketed identified predicate device.