February 22, 2023

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

Re: K221903
Trade/Device Name: Delta III Pro Lithotripter
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: January 25, 2023
Received: January 25, 2023

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 -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

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)*

K221903

Device Name

Delta III Pro Lithotripter

Indications for Use *(Describe)*

The Delta III Pro Lithotripter is indicated for the fragmentation of urinary tract stones, i.e., renal calyceal stones, renal pelvic stones, and upper ureteral stones.

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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SECTION V

510(k) SUMMARY Delta III Pro Lithotripter

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

Dornier MedTech America
1155 Roberts Blvd.
Kennesaw, GA 30144
Date Prepared: 06/27/22
Contact Person: John Hoffer Phone: 770-514-6163

Name of Device and Name/Address of Sponsor
Delta III Pro Lithotripter
Dornier MedTech America, Inc. 1155 Roberts Blvd.
Kennesaw, GA 30144

Common or Usual Name
Shock Wave Lithotripter

Classification Name
According to 21 C.F.R. § 876.5990, FDA has classified extracorporeal shock wave lithotripters as Class II devices with special controls. The Product Code for these lithotripters is LNS.

Predicate Device
Dornier Delta III Lithotripter (K201074)

Purpose of the 510(k) Notice
The Delta III Pro Lithotripter that is the subject of this submission is a modification to the Dornier Delta III Lithotripter (K201074) to include the following minor changes:

- Offering as an option the use of a Flat Panel detector in place of the Image Intensifier
- Offer an optional ECG Unit due to the obsolescence of the current optional ECG Model offered

The modified Delta III Pro has the same intended use, technological characteristics, and principles of operation as the predicate device. The difference between the modified Delta III Pro and the predicate device does not raise any new or different questions of performance, safety or effectiveness. Thus, Dornier believes that the modified Delta III Pro is substantially equivalent.

Intended Use/Indications for Use
The Delta III Lithotripter Pro is indicated for the fragmentation of urinary tract stones, i.e., renal calyceal stones, renal pelvic stones, and upper ureteral stones.

Device Description

The Delta III Pro Lithotripter is a modular urological work station designed for extracorporeal shock wave lithotripsy ("ESWL") and for diagnostic and therapeutic procedures usual in urology.

The Delta III is composed of the following modules:

- Basic Unit with integrated X-ray C-arm and Therapy Arm with camera for Shockwave Treatment;
- Patient Table;
- Control Desk/Image Storage (UIMS).

The basic unit contains the power supplies, control unit, power electronics for motor drives, components for shockwave generation, and an integrated Therapy C-arm and an X-Ray C-Arm. The housing can be positioned with its back close to the room wall and has wide side doors for easy service.

The therapy and X-ray C-arm house the shock wave source ("EMSE") and the complete X- ray unit. The X-ray unit consists of the X-ray generator, the X-ray tube, a flat panel image receptor system, and a high resolution imaging chain. This provides the imaging to perform the procedures. The C-arms allow for a wide range of movement to facilitate performing urological procedures. The shock wave circuit supplies the shock wave energy needed for the treatment of kidney stones.

The Delta III Pro's urological patient table provides longitudinal, lateral and vertical travel range to allow easy positioning of the stone in the shock wave focus for lithotripsy and urological procedures.

The image processing system (UIMS) with DICOM 3 capability supports PACS connection and offers complete X-ray control and image handling.

All of the characteristics described above of the Delta III Pro subject to this submission are equivalent to the predicate device.

Technological Characteristics
As described in the section above, the Delta III Pro device has the same technical characteristics as the predicate. This includes function and operation of the three main modules that comprise the system, the Basic Unit with integrated X- ray C-arm and Therapy Arm with camera for Shockwave Treatment, the Patient Table and the Control Desk and Image Processing ability. The minor changes that are associated with this submission does not change the essential function and use of the Delta III Pro as compared to the predicate.

Performance Data
The company has complied with all of the requirements described in FDA's Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.

The device is in compliance with the following standards:

- IEC 60601-1:2006/AC:2010+A1:2013,Electrical safety of medical devices;
- IEC 60601-1-2: 2015, Electromagnetic compatibility;
- IEC 60601-1-3: 2008, Radiation protection in diagnostic X-ray equipment;
- IEC 60601-2-36:2014, Safety of equipment for extracorporeally induced lithotripsy;
- IEC 60601-2-54:2009 + Cor.:2010 + Cor.:2011, Medical electrical equipment - particular requirements for the basic safety and essential performance of x-ray equipment;
- IEC 62366-1:2015 + COR1:2015, Medical Devices Part 1: Application of usability engineering to medical devices.

In summary, during the verification testing, the electrical safety of the system, electromagnetic compatibility and usability issues were fully addressed by demonstrating compliance with the appropriate standards. There were no unanticipated new risks identified

Software Verification and Validation Testing:
The software used in the Delta III Pro has the identical functionality as in the predicate Delta III device. Documentation for a Moderate Level of Concern per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on November 4, 2021 is also included as part of this submission.

Clinical testing is not necessary for the subject device, based on the same basic technology as the predicate device and based on the minor differences. Successful bench testing results demonstrate substantial equivalence to the predicate device. All non-clinical functional testing successfully passed and met all design requirements.

The results of the non-clinical performance standards and testing support that the device can be used safely and effectively.

Conclusions

The Delta III Pro is as safe and effective as the cited predicate device. The Delta III Pro has the same intended uses and indications, technological characteristics, and principles of operation as its predicate device. The minor differences do not alter the intended the use of the device and does not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the Delta III Pro and its predicate device raise no new or different questions of safety or effectiveness. Design controls demonstrate that the Delta III Pro is as safe and effective as the predicate device. Thus, the Delta III Pro is substantially equivalent.