September 3, 2020

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

Re: K201074
Trade/Device Name: Delta III Lithotripter
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal Shock Wave Lithotripter
Regulatory Class: II
Product Code: LNS
Dated: August 4, 2020
Received: August 6, 2020

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K201074

Device Name

Delta III Lithotripter

Indications for Use *(Describe)*

The Delta III 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 Lithotripter

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

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

Date Prepared: August 3, 2020

Contact Person: John Hoffer Phone: 770-514-6163

Name of Device and Name/Address of Sponsor

Delta III 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 (K172084)

Purpose of the 510(k) Notice
The Delta III Lithotripter that is the subject of this submission is a modification to the Dornier Delta III Lithotripter (K172084) to include the following minor changes:

- Replacement of Image Intensifier camera for X-Ray as a result of the current models obsolescence,
- Replacement of operating system Windows 7 with Windows 10,
- Update the UIMS system to incorporate the AGFA MUSICA software package to enhance and improve the X-Ray image processing.
- Offer the optional ultrasound unit (SonoScape X3 Pro with transducer 510(k) K163427).due to the obsolescence of the current BK Ultrasound Model.

The modified Delta III has the same intended use, technological characteristics, and principles of operation as the predicate device. The difference between the modified Delta III 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 is substantially equivalent.

Intended Use/Indications for Use
The Delta III Lithotripter 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 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, an 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'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 subject to this submission are identical to the predicate device.

Technological Characteristics

As described in the section above, the Delta III 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 do not change the essential function and use of the Delta III as compared to the predicate.

Performance Test Data

Standards Testing

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 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012,Electrical safety of medical devices;
- IEC 60601-1-2: 2014, Electomagnetic 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 60601-2-28:2010 Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- 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; and
- IEC 62366-1:2015 + COR1:2016, Medical Devices Part 1: Application of usability engineering to medical devices.
- IEC/TR 62366-2:2016 Medical devices — Part 2: Guidance on the application of usability engineering to medical devices

Bench Testing

The company has performed functional validation testing to assure the modifications do not impact the performance of the equipment. These tests included:

1. Evaluate the performance of the new ultrasound device to assure it provides visual and accurate images for stone visualization.
2. Compare the images from the new camera to assure the image quality is equal to or better than the predicate
3. Validate the UIMS software to demonstrate the inclusion of the AGFA software package does not impact any functioning of the equipment and provides the ability to further process the x-ray images

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

Conclusions

The Delta III is as safe and effective as the cited predicate device. The Delta III 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 do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the Delta III and its predicate devices raise no new or different questions of safety or effectiveness. Design controls demonstrate that the Delta III is as safe and effective as the predicate device. Thus, the Delta III is substantially equivalent.