



Food and Drug Administration
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August 8, 2017

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

Re: K172084
Trade/Device Name: Delta III Lithotripter
Regulation Number: 21 CFR 876.5990
Regulation Name: Extracorporeal Shock Wave Lithotripter
Regulatory Class: Class II
Product Code: LNS
Dated: July 10, 2017
Received: July 10, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)

K172084

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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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: July 10, 2017

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 (K170122)

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 (K170122) to include the following minor changes:

- The UIMS cart wheels were required to be replaced as a result of their obsolescence,
- Several electronic components were required to be modified or upgraded as a result of additional IEC electrical testing,
- In order to affix the CE Mark, the power rating label of the Delta III X-ray device had to be changed to reflect the effective power as measured instead of the actual power input level.

- A modification to the collision system was required due to instances when the restoring force relating to the collision system is too low, the collision system output signal remains in "collision mode" even though the collision situation has been corrected.
- For user convenience and preference, a software change was made that allows the user to utilize fluoroscopy without significant delay directly after a snap shot is taken,
- Additional Ultrasound base units are now being offered to use with the identical ultrasound transducer, and
- A easier applied inner coating lining of the hand controller has been implemented.

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 Processing.

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 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 60601-1:2005, Electrical safety of medical devices;
- IEC 60601-1-2:2007, Electromagnetic compatibility;
- IEC 60601-1-3: 2008, Radiation protection in diagnostic X-ray equipment;
- IEC 60601-2-36: 1997, Safety of equipment for extracorporeally induced lithotripsy;
- IEC 61846, Ultrasonics - pressure pulse lithotripters characteristics of fields;
- IEC 60601-2-54, Medical electrical equipment - particular requirements for the basic safety and essential performance of x-ray equipment; and
- Usability: IEC 62366:2007, Application of usability engineering to medical devices.

In summary, during the verification testing, the electrical safety of the system and the electromagnetic compatibility were fully addressed by demonstrating compliance with the applicable standards. In addition, appropriate software verification testing, testing to sections of IEC 60601-1 for wheel performance and collision protection, and verification of hand controller function testing were also performed to address the modifications made that are subject to this submission.

Also, an engineering analysis concluded that the prior ultrasound localization accuracy testing supported the compatibility of the additional ultrasound systems that were added.

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.