June 28, 2017

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

Re: K170122
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: May 26, 2017
Received: May 26, 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,

Benjamin R. Fisher -S

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
Indications for Use

510(k) Number (if known)

K170122

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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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: January 12, 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 Compact Delta Lithotripter (P840008, S065/066)

**Reference Devices**

Dornier Gemini 220 XXP-HP Lithotripter (K151298)  
GE OEC 9900 Elite C-Arm (K122234)

**Purpose of the 510(k) Notice**

The Delta III Lithotripter is a modification to the Dornier Compact Delta Lithotripter (P840008, S065/066) to allow for the use of an alternate EMSE source, a larger X-Ray generator tube and to include a camera (Opticouple) feature to view the patient to bellows coupling interface.

**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 Lithotripter 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 Lithotripters’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. It is essentially the same as in the predicate device.

The image processing system (UIMS) with DICOM 3 capability supports PACS connection and offers complete X-ray control and image handling. This image processing system is the same as used for the other referenced Dornier predicate devices.

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, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- IEC 60601-2-36:2014, Particular requirements for the safety of equipment for extracorporeally induced lithotripsy;
- IEC 61846 First edition 1998-04, Ultrasonics - pressure pulse lithotripters - characteristics of fields;
- IEC 60601-2-54 Edition 1, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy.
In summary, during the design and verification testing, the acoustic output of the EMSE, the electrical safety of the system and any electromagnetic compatibility issues were fully addressed by demonstrating compliance with the appropriate standards. There were no unanticipated risks identified. Lastly, the device manual was reviewed and approved as part of the design control process. It contains all necessary warnings, cautions and instructions to mitigate potential injuries.

Clinical Data

A retrospective confirmatory clinical study was performed using the Delta III Lithotripter. As compared to the currently cleared Dornier Lithotripters, the overall treatment results were comparable for the subject device. The complication rate was extremely low.

Substantial Equivalence

The Delta III Lithotripter has the same indications for use as the predicate Dornier Compact Delta Lithotripter (P840008, S065/66) and subsequent reference devices, such as the Dornier Gemini 220 XXP-HP EMSE Lithotripter (K151298). The Delta III Lithotripter also has the same technological characteristics as the predicate Dornier Compact Delta Lithotripter (P840008 S065/66), to which it is a modification. The Delta III Lithotripter and the predicates are extracorporeal shock wave lithotripters used for fragmentation of urinary tract stones, i.e., renal calyceal stones, renal pelvic stones, and upper ureteral stones. The technology to perform this function involves use of an electromagnetic shock wave emitter (“EMSE”). This basic technology is identical in the subject device and the Dornier predicate and reference devices. In the case of the shock wave source parameters, the characteristics of the subject device are substantially equivalent to the parameters of the Dornier Compact Delta Lithotripter with the 140f EMSE (P840008, S065/66), and the Dornier Gemini 220 XXP-HP EMSE Lithotripter (K151298).

The other primary element of the Delta III Lithotripter, the integrated X-ray unit, has a slightly larger X-ray generator (15kW vs. 3.5kW), which is designed to produce better imaging capabilities. This size generator is well within the range of other cleared X-ray components, such as the GE OEC 9900 Elite C-Arm (K122234). Other than this modification, the X-ray component, including the imaging chain, is the same as the referenced Dornier predicates. This modified component performs the same function and operates in the same manner during the procedures involved in the fragmenting of urological stones.

The Delta III Lithotripter also includes an integrated camera to view in real time the integrity of the patient to bellows coupling interface. The camera feature is identical to that found on the Dornier Gemini XXP-HP lithotripter, which was previously cleared in 510(k) K151298.

The urological patient table, which provides longitudinal, lateral and vertical travel range, allows easy positioning of the stone in the shock wave focus for lithotripsy and urological procedures is the same manner as in the predicate devices. The image processing system (UIMS) is also the same as used in the Dornier predicates.

Conclusion

From a clinical perspective and comparing design specifications, the Delta III Lithotripter and the predicate devices are substantially equivalent and have the same intended use. The differences between the subject and predicate devices do not raise any concerns regarding the overall safety or effectiveness. Thus, the Delta III Lithotripter is substantially equivalent to its predicate device.