



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

July 30, 2015

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

Re: K151298  
Trade/Device Name: Gemini XXP-HP  
Regulation Number: 21 CFR 876.5990  
Regulation Name: Extracorporeal Shock Wave Lithotripter  
Regulatory Class: II  
Product Code: LNS  
Dated: May 18, 2015  
Received: May 19, 2015

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 yours,

**Herbert P. Lerner -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)

K151298

Device Name

**Dornier Gemini XXP-HP**

Indications for Use (Describe)

The Gemini XXP-HP 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)  
Subpart C)

Over-The-Counter Use (21 CFR 801

**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.

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510(k) SUMMARY  
Gemini XXP-HP Lithotripter

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

Dornier MedTech America                      Phone: 770-514-6163  
1155 Roberts Blvd.                              Fax: 770-514-6291  
Kennesaw, GA 30144                            Date Prepared: May 14, 2015

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

Name of Device and Name/Address of Sponsor

Gemini 220 XXP-HP  
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 Gemini 220 XP Lithotripter (K132672)

Reference Devices

Storz Modulith SLX-F2 180 (K072788)  
Siemens Lithoskop/Pulso (K070665)

Purpose of the 510(k) Notice

The Gemini XXP-HP is a modification to Dornier's Gemini 220 XP Lithotripter (K132672) to allow the use of an alternate EMSE source and to reintroduce the camera (Opticouple) feature to view the patient to bellows coupling interface.

Intended Use

The Gemini XXP-HP is indicated for the fragmentation of urinary tract stones, i.e., renal calyceal stones, renal pelvic stones, and upper ureteral stones.

Device Description

The Gemini XXP-HP is a modular urological work station designed for extracorporeal shock wave lithotripsy ("ESWL") and for diagnostic and therapeutic procedures usual in Urology.

The Gemini XXP-HP is composed of the following modules:

- Basic Unit with integrated X-ray C-arm and Therapy Arm for Shockwave Treatment;
- Patient Table;
- Control Desk – User Interface.

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 Gemini XXP-HP’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 the same as in the predicate device.

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

#### 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 (i.e., the special control guidance document).

The device is in compliance with the following standards:

- IEC 60601-1:2007 Electrical safety of medical devices
- IEC60601-1-2:2007 Electromagnetic compatibility
- IEC 60601-1-3:2008 Radiation protection
- IEC 60601-1-6:2008 Usability
- IEC 60601-2-7 Safety of high-voltage generators of diagnostic X-ray generator
- IEC 60601-2-28 Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
- IEC 60601-2-36:1997 Extracorporeally induced Lithotripsy
- IEC 60601-2-32:1995 Safety of X-ray equipment
- IEC 61846 Ultrasonics – Pressure pulse lithotripters characteristic of fields

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. Additionally, verification and validation testing of the modified system software was successfully completed. 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

According to the recommendations of the special control guidance document, a confirmatory clinical study was performed using the Gemini XXP-HP to confirm the usability, safety, and effectiveness of this modified lithotripter. As compared to the conventional EMSE (penetration depth 150mm), both mean number of shockwaves and mean energy level were slightly lower with the subject device. Overall treatment results were comparable with a slight advantage for the Gemini XXP-HP:

The complication rate was extremely low. Beside expected pain, no further complications were observed. No shock wave-induced hematoma or shock wave related complications were encountered.

### Substantial Equivalence

The Gemini XXP-HP has the same technological characteristics as the predicate Dornier Gemini 220 XP Lithotripter (K132672), to which it is a modification. The Gemini XXP-HP and the predicate 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. In the case of the shock wave source parameters, the characteristics of the subject device are substantially equivalent to those for the Storz Modulith SLX-F2 180 (K072788) and the Siemens Lithoskop/Pulso (K070665). The other primary elements of the Gemini XXP-HP, *i.e.*, the patient table and the X-ray unit, are the same to that of the Dornier predicate. They perform the same function and operate in the same manner during the procedures involved in the fragmenting of urological stones. The Gemini XXP-HP also includes a camera to view in real time the integrity of the patient to bellows coupling interface. The camera feature is directly comparable to that of the Dornier Model HM3 lithotripter, which was previously approved (P840008 S18) prior to the downclassification of lithotripters to class II.

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