



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Dornier MedTech America Incorporated  
Mr. John Hoffer  
Vice President Quality, Regulatory, Clinical  
1155 Roberts Boulevard, Suite 100  
Kennesaw, Georgia 30144

October 8, 2015

Re: K152591  
Trade/Device Name: Dornier Medilas H RFID Laser Fiber  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology  
Regulatory Class: Class II  
Product Code: GEX  
Dated: September 9, 2015  
Received: September 10, 2015

Dear Mr. 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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); 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" (21CFR 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,

**Joshua C. Nipper -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use Statement

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)

K152591

Device Name

Dornier Medilas H RFID Laser Fiber

Indications for Use (Describe)

Dornier's Medilas H RFID Laser Fibers are intended to be used as an accessory for the Dornier Medilas H Holmium Laser ("Laser"). This laser is intended for cutting, vaporization, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopes), or for open surgery for contact or non-contact surgery with or without a handpiece for use in incision/excision, vaporization, ablation and coagulation of soft tissue. The Laser is indicated for use in medicine and surgery, in the following medical specialties:

- Arthroscopy
- Urology
- Lithotripsy
- Pulmonology
- Gastroenterology
- Gynecology
- ENT
- General Surgery

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****Dornier's Medilas H RFID Laser Fiber****Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

Dornier MedTech America 1155 Roberts Blvd. Kennesaw, GA 30144	Phone: 770-514-6163 Fax: 770-514-6291 Date Prepared: September 1, 2015
Contact Person: John Hoffer	Phone: 770-514-6163

**Name of Device and Name/Address of Sponsor**

Medilas H RFID Laser Fibers  
John Hoffer  
Dornier MedTech America  
1155 Roberts Blvd.  
Kennesaw, GA 30144

**Common or Usual Name**

Holmium Laser Fibers

**Classification Name**

Laser Instrument, (Accessory); Product Code: GEX

**Predicate and Reference Devices**

Dornier Medilas H RFID Laser Fiber (K121938) (Primary predicate device)  
Bard Endobeam Laser Fibers (K120926)

**Purpose of the Special 510(k) notice.**

The Medilas H RFID Laser Fiber is a modification to Dornier's currently cleared Dornier Medilas H RFID Laser Fibers (K121938) to include a fiber with a reduced outer diameter.

**Intended Use/Indications for Use**

Dornier's Medilas H RFID Laser Fibers are intended to be used as an accessory to the Dornier Medilas H Holmium Laser ("Laser"). This laser is intended for cutting, vaporization, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopes), or for open surgery for contact or non-contact surgery with or without a handpiece for use in incision/excision, vaporization, ablation and coagulation of soft tissue. The Laser is indicated for use in medicine and surgery, in the following medical specialties:

- Arthroscopy,
- Urology,

- Lithotripsy,
- Pulmonology,
- Gastroenterology,
- Gynecology,
- ENT,
- General Surgery.

### **Technological Characteristics**

The Dornier's Medilas H RFID Laser Fiber has the same technological characteristics and principles of operation as the predicate devices. The fiber core and cladding for the subject device are made from silica, which is same material used in all the predicate devices. Additionally, the fiber is manufactured and tested in the identical fashion as the company's predicate device and functions in an equivalent manner.

### **Performance Data**

Nonclinical functional performance testing was conducted per internal test methods. The functional testing included:

- Power transmission testing
- Durability Stress Testing
- Eccentricity Testing
- Visual Inspections

These methods were the same as used for the cleared predicate.

### **Substantial Equivalence**

Dornier's Medilas H RFID Laser Fiber has the same intended use/indications for use, as well as technological characteristics and principles of operation as the predicate devices. The minor difference of laser fiber outer diameter size does not raise any new questions of safety or effectiveness. Performance data demonstrates that the Dornier Medilas H RFID Laser Fibers are substantially equivalent to the listed company predicate device. Thus, the Dornier Medilas H RFID Laser Fibers are substantially equivalent to its predicate and reference devices.