DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 28, 2016

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

Re: K161771
Trade/Device Name: Medilas H Laser Fibers
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: June 26, 2016
Received: June 28, 2016

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 Part 801 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,

Christopher J. Ronk -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)*
K161771

Device Name
Dornier Medilas H RFID Gentle Flex 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)*	
X 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: June 26, 2016

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

Name of Device and Name/Address of Sponsor

Medilas H RFID Gentle Flex 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 (K152591) (Predicate device)
Boston Scientific Flexiva TracTip Laser Fiber (K110685) (Reference device)

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 (K152591) to include a rounded, ball tip, distal end.

Intended Use/Indications for Use

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.

Technological Characteristics

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

Standards

ISO 14971:2007 Medical devices -- Application of risk management to medical devices
ISO 10993-1:2009 Biological evaluation of medical devices
ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide

Performance Data

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

- Confirming that the emission pattern of the distal tip from the laser colored aiming beam is equivalent to the predicate device;
- Confirming the power transmission of the laser fibers when used with a Dornier Medilas H30 Holmium Laser is equivalent to the predicate device;
- Confirming the tip fracture resistance of the ball tip fiber is equivalent to the predicate device; *and*
- Confirming the ability of the ball tip laser fibers to be introduced into a deflected scope with minimal resistance.

Substantial Equivalence

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