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K061455

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Dornier *Medilas H 20* Laser

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

1. General Information

Submitter Information:	Dornier MedTech America, Inc. 1155 Roberts Boulevard Kennesaw, Georgia 30144 U.S.A.
Contact Person:	Tim Thomas
Contact Phone Number:	(770) 514-6163
Contact Fax Number:	(770) 514-6288
Summary Preparation Date:	May 19, 2006

2. Device Name

Proprietary Name:	Dornier *Medilas H 20* Laser
Common Name:	Holmium: Yttrium Aluminum Garnet (HO:YAG) Laser System
Classification Name:	Laser Instrument, Surgical, Powered (Product Code GEX)

3. Predicate Devices

- Dornier *Medilas H* Laser (K981718)
- Trimedyne *OmniPulse Mini*, Model 2120 Holmium:YAG Laser System (K043012)
- Lumenis *VersaPulse PowerSuite* Holmium Surgical Laser and Delivery Devices with Accessories (K011703)

4. Device Description

The Dornier *Medilas H 20* Laser is a pulsed solid-state Holmium:YAG laser system. The Dornier *Medilas H 20* Laser emits laser radiation in the invisible wavelength range of 2080 nm in either a continuous-wave or pulsed mode, which is absorbed primarily by water, with an average penetration depth of approximately 400µm (0.4mm). The Dornier *Medilas H 20* Laser incorporates a graphic display panel with touch screen capabilities allowing the operator to control the functions and laser parameters of the laser. The laser pulse control panel regulates the pulse energy, pulse frequency, pulse mode (continuous mode, pedal-controlled repetitive burst mode and control panel bursts mode), pilot brightness, and various Menu functions. The Dornier *Medilas H 20* Laser light emission is transmitted to the application site by a sterile fiber optic delivery systems or fiber optic cables with a SMA 905 connector.

5. Intended Use

The Dornier *Medilas H 20* Laser is designed for use in conjunction with various fiber optic cables as a laser system. The modified Dornier *Medilas H 20* Laser and currently marketed Dornier *Medilas H* Laser are intended to be used 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 Dornier *Medilas H 20* Laser is indicated for use in medicine and surgery, in the following medical specialties:

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

6. Technological Characteristics

The proposed Dornier *Medilas H 20* Laser is substantially equivalent to the predicate devices Trimedyne *OmniPulse Mini*, Model 2120 Holmium:YAG Laser System (K043012) and Lumenis *VersaPulse PowerSuite* Holmium Surgical Laser and Delivery Devices with Accessories (K011703) in device design, technology characteristics, and operational characteristics as provided in the Premarket Notification. Some of the Technology characteristics described include:

Principles of Operation: The Dornier *Medilas H 20* Laser and all predicate lasers have same basic operational features for Holmium YAG lasers with flash lamp emission.

Laser Type: The Dornier *Medilas H 20* Laser and all predicate lasers are Solid State Holmium HO:YAG lasers which are equivalent.

Maximum Radiant Power: The Dornier *Medilas H 20* Laser and all predicate lasers have a maximum of 20 Watts radiant power wattage which are equivalent.

Wavelength: The Dornier Medilas H 20 Laser has a wavelength of 2080nm and all predicate lasers operate at 2100nm which are equivalent.

Energy Output: The Dornier *Medilas H 20* Laser and all predicate lasers have energy outputs between 1.8J to 2.5J which are equivalent.

Pulse Duration: The Dornier *Medilas H 20* Laser has a pulse duration of 350us and all predicate lasers have pulse durations between 250us – 500us which are equivalent.

Cooling Method: The Dornier *Medilas H 20* Laser has an integrated water cooling system with water/air exchangers and all predicate lasers have integrated water cooling system with water/air exchangers which are equivalent.

Operational Modes: The Dornier *Medilas H 20* Laser and all predicate lasers have continuous and pulse modes which are equivalent.

Delivery Systems: The Dornier *Medilas H 20* Laser and all predicate lasers use equivalent ethylene oxide sterilized fiber optic delivery systems with a SMA 905 connector that are used in conjunction with endoscopes for target visualization.

7. Rational for Substantial Equivalence

The Dornier *Medilas H 20* Laser has the same indications for uses as the predicate device Dornier *Medilas H* Laser (K981718). The Dornier *Medilas H 20* Laser has the same general indications for uses as the predicate devices Trimedyne *OmniPulse Mini*, Model 2120 Holmium:YAG Laser System (K043012) and Lumenis *VersaPulse PowerSuite* Holmium Surgical Laser and Delivery Devices with Accessories (K011703). There is no safety of efficacy concerns with the indications for use statements as presented.

8. Safety and Effectiveness Information

Safety and effectiveness information was provided in the Premarket Notification to demonstrate that the Dornier *Medilas H 20* Laser is safe and effective, when indicated for use for general and specific applications in the medical specialties of Arthroscopy, Urology, Lithotripsy, Pulmonology, Gastroenterology, Gynecology, ENT, and General Surgery.

9. Conclusion

The Dornier *Medilas H 20* Laser was determined to be substantially equivalent to similar current marketed and predicate surgical lasers. The Dornier *Medilas H 20* Laser has the same indications for uses as the predicate device Dornier *Medilas H* Laser (K981718). The Dornier *Medilas H 20* Laser has the same general indications for uses as the predicate devices Trimedyne *OmniPulse Mini*, Model 2120 Holmium:YAG Laser System (K043012) and Lumenis *VersaPulse PowerSuite* Holmium Surgical Laser and Delivery Devices with Accessories (K011703).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2006

Dornier MedTech America, Inc.
% Mr. Tim Thomas
Vice President of Quality, Regulatory
& Clinical
1155 Roberts Boulevard
Kennesaw, Georgia 30144

Re: K061455
Trade/Device Name: Dornier Medilas H 20 Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 19, 2006
Received: July 1, 2006

Dear Mr. Thomas:

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.

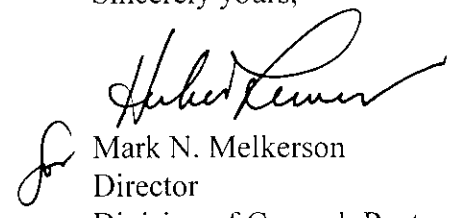
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Dornier MedTech America, Inc.

Dornier *Medilas H 20* Laser System

INDICATIONS FOR USE

510(k) Number (if known): K061455

Device Name: Dornier *Medilas H 20* Laser

Indications for Use:

The Dornier *Medilas H 20* Laser is intended to be used 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 Dornier *Medilas H 20* Laser is indicated for use in medicine and surgery, in the following medical specialties:

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

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices