

NOV 25 1998

K983963

**510(k) SUMMARY
Dornier Surgical Products, Inc's
Medilas H Pulsed Laser**

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

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Carol Wernecke
Director of Regulatory and Clinical Affairs
1155 Roberts Boulevard
Kennesaw, GA 30144

Date Prepared: November 5, 1998

Name of Device and Name/Address of Sponsor

Medilas H Pulsed Holmium YAG Laser

Dornier Surgical Products, Inc.
1155 Roberts Boulevard
Kennesaw, GA 30144

Classification Name

HO: FDA has not specifically classified YAG lasers.

Predicate Devices

Unmodified Dornier Medilas H Laser

Intended Use

The Dornier Medilas H Laser is intended to be used in cutting, vaporization, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopes), or in incision/excision, vaporization, ablation and coagulation of soft tissue in contact or non-contact open surgery (with or without hand piece).

The Dornier Medilas H Laser is indicated for use in medicine and surgery, in the following specialties: Urology, Pulmonology, Arthroscopy, Lithotripsy, Gastroenterology, Gynecology, ENT, and General Surgery.

Technological Characteristics and Substantial Equivalence

The Dornier Medilas H Pulsed Holmium YAG Laser is a compact pulsed HO: YAG laser emitting laser radiation in the invisible range of 2080 nm. The Medilas H provides a temperature-controlled method for contact cutting and non-contact coagulation and vaporization with a bare fiber.

The modified Medilas H has the same principles of operation and similar technological characteristics as the previously unmodified Medilas H (K981718).

The modified Medilas H and the unmodified Medilas H laser systems have photoelectric power meters and are automatically calibrated. They also have a 2-stage waterproof and explosion proof footswitch and both lasers incorporate a watchdog-monitored microprocessor.

Both Lasers depict a graphic display panel which show the laser operating parameters, application modes, time functions, system status and messages for the user.

The Medilas H lasers provide a temperature controlled method for contact cutting and non-contact coagulation and vaporization with fibers made of quartz glass with a bare fiber tip. These fibers are available in diameters of 400 and 600 μm .

The Medilas H lasers feature one mode of operation: Standard. The microprocessor controlled Dornier Medilas H lasers have been developed in accordance with the latest technical standards.

The lasers have a cooling system that includes an air-cooled, temperature controlled, internal closed circuit water system. The cooling systems are identical as concurred in 510(k) # K981718.

As a safety feature, both Medilas H lasers have a single rotating magnetic shutter which moves the filter out of the laser beam. One microprocessor controls the shutter. The Medilas H lasers contain a single shutter with two parallel running microprocessors. Whenever one microprocessor runs differently from the other, the Medilas H laser

hardware initiates a “system fault” routine. During any “system fault” laser production and release immediately halt.

There are minor differences between the Medilas H laser, and the unmodified cleared Medilas H laser (K981718). The modified laser system aiming beam is 635 nm, maximum power at aperture 1mW and the unmodified cleared Medilas H laser aiming beam is 630 nm, maximum power at aperture 1mW. The modified Medilas H is contained in new housing. The dimensional specification is visually different from the predicate (unmodified Medilas H) laser system. These modifications do not present any new issues of safety or effectiveness of the device.

Performance Data

While no performance standard have been established for HO: YAG lasers under Section 514 of the Federal Food, Drug and Cosmetic Act, the Dornier Medilas H laser is in compliance with class IV performance standards for light emitting products promulgated under the Radiation Control Health and Safety Act of 1968. See 21 C.F.R. § 1040.10 and §1040.11. The laser also complies with the applicable requirements of the following voluntary standards: IEC-601, IEC 825/VDE 0837/2.86.

Advisory:

This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Carol Wernecke
Director
Regulatory and Clinical Affairs
Dornier Medical Systems, Inc
1155 Roberts Boulevard
Kennesaw, Georgia 30144

Re: K983963
Trade Name: Dornier Medilas H Laser (Modified)
Regulatory Class: II
Product Code: GEX
Dated: November 05, 1998
Received: November 06, 1998

Dear Ms. Wernecke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

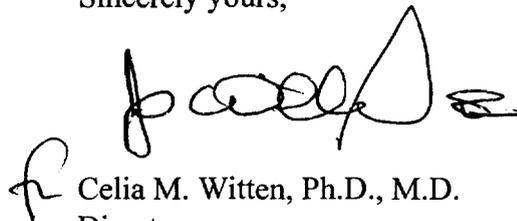
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Carol Wernecke

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and a long horizontal stroke at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: K983963
~~K981718~~-Special 510(k): Device Modification

Device Name: Modified Dornier Medilas H Laser

Indications for Use:

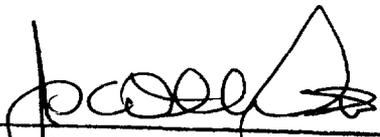
The Dornier Medilas H Laser is intended to be used in cutting, vaporization, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopes), or in incision/excision, vaporization, ablation and coagulation of soft tissue in contact or non-contact open surgery (with or without hand piece).

The Dornier Medilas H is indicated for use in medicine and surgery, in the following medical specialties:

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use X or Over-the-Counter Use _____



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983963