3/26/99 K 984591

510(k) SUMMARY
Dornier Surgical Products, Inc's
Medilas H/2 Laser

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

Walter Payerl, President
1155 Roberts Boulevard
Kennesaw, GA 30144
Phone: (770) 426-1315
Facsimile: (770) 514-6288

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

Date Prepared: March 23, 1999

Name of Device and Name/Address of Sponsor

Medilas H/2 Laser

Dornier Medical Systems, Inc.
1155 Roberts Boulevard
Kennesaw, GA 30144

Classification Name

FDA has not specifically classified Ho:YAG lasers.

Predicate Devices

Dornier Medilas H Laser System (K983963)

Intended Use

The Dornier Medilas H/2 Laser is intended to be used in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparascopes, 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/2 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

From a clinical perspective and comparing design specifications, the Dornier Medilas H/2 Laser and the predicate devices are substantially equivalent and have the same intended use. The minor difference between the two laser systems is the replacement of a contraindication with a precaution statement regarding its use in fragmentation of kidney and bladder stones. Based on the technological characteristics and overall performance of the devices, Dornier Surgical Products, Inc. believes that no significant differences exist between the Dornier Medilas H/2 and the predicate devices: the Dornier Medilas H (K983963).

Dornier Surgical Products, Inc believes the minor differences of the Dornier Medilas H/2 and its predicate laser devices should not raise any concerns regarding the overall safety or effectiveness.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 1999

Dornier Surgical Products, Inc.
c/o Ms. Carol Wernecke
Director of Regulatory and Clinical Affairs
Dornier Medical Systems, Inc.
1155 Roberts Boulevard
Kennesaw, Georgia 30144

Re: K984591
Trade Name: Dornier Medilas H/2 Laser
Regulatory Class: II
Product Code: GEX
Dated: December 22, 1998
Received: December 28, 1998

Dear Ms. Wernecke:

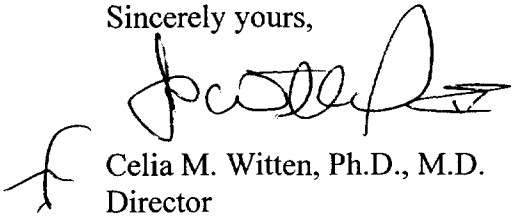
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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.

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/dsmamain.html".

Sincerely yours,



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: K 984591

Device Name: Dornier Medilas H/2 Laser

Indications for Use:

The Dornier Medilas H/2 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 K984591