

K982629

SEP 14 1998

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Dornier Surgical Products, Inc.'s Medilas D Laser**

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Dornier Medilas D Laser is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which includes the following: Dornier 5100 Laser (K964760) and Indigo's 830e (K955758).

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

Dornier Surgical Products, Inc.	Phone: 770-426-1315
10027 South 51 st Street	Facsimile: 770-514-6288
Phoenix, AZ 85044	
Contact Person: Carol Wernecke	Date Prepared: July 21, 1998

Name of Device and Name/Address of Sponsor

Dornier Medilas D Laser
Dornier Surgical Products, Inc.
10027 South 51st Street
Phoenix, AZ 85044

Classification Name

Diode lasers have not been specifically classified by FDA.

Predicate Devices

Dornier Medilas Fibertome Laser Model 5100 and Indigo's 830e Laser

Intended Use

The Dornier Medilas D 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 D Laser is indicated for use in medicine and surgery, in the following specialties: Urology, Plastic Surgery, Dermatology, Radiology, Pulmonology, Gastroenterology, Gynecology, ENT, and General Surgery.

Technological Characteristics and Substantial Equivalence

The Dornier Medilas D laser and its predicate device, the Dornier 5100 has the same intended use. Both lasers 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 in incision/excision, vaporization, ablation and coagulation of soft tissue in contact or non-contact open surgery (with or without hand pieces). Both devices are indicated for use in medicine and surgery.

The Dornier Medilas D laser has the same principles of operation and similar technological characteristics as the previously cleared predicates, Dornier 5100 laser. The Medilas D is a 50 W laser while the 5100 laser is a 100 W laser. Both devices are continuous-wave, emitting laser radiation in the invisible ranges of 940 nm (Medilas D) and 1064 nm (5100). The Medilas D offers laser power of 0-50 W at the distal tip of the light guide, adjustable in 1 W steps. The 5100 offers laser power of 2-100 W at the distal tip of the light guide, adjustable in 1 W steps. Both laser offers adjustable pulse duration. The Medilas D and the 5100 laser offers the same software controlled operating modes with exception to the Medilas D, it does not have the same number of operating modes as the 5100 laser.

The Medilas D is calibrated during the manufacturing process and during service calls. The end-user does not calibrate fibers for this system. The 5100 laser has a photoelectric power meter and is automatically calibrated. Both lasers have a 2-stage waterproof and explosion-proof switch and both laser incorporates a watchdog-monitored microprocessor.

There are minor differences between the Medilas D laser and the predicate 5100 laser, none of which present new issues of safety or effectiveness. The minor differences are discussed in detail below.

The Medilas D and the 5100 laser use very similar aiming beams. The Medilas D uses a 0.1mW Diode laser aiming beam with a wavelength of 645 nm. The 5100 laser uses a 2 mW Diode laser aiming beam with a

wavelength of 630 nm. The maximum power of both aiming beams at the aperture is 1 mW. The minor differences in wavelengths between the treatment beams do not raise new issues of safety or effectiveness since the aiming beam does not affect the tissue. The aiming beams merely provide visual indication of the location at which the treatment beam will strike the tissue.

Both the Medilas D and the 5100 laser incorporate a graphic display panel. The graphic display shows laser operating parameters, application modes, time functions, system status and messages for the user.

Like its predicated device, the Medilas D laser offers several software controlled operating modes. Most of the operating modes are identical to those offered in the predicate device, the 5100 laser. Both lasers include the following operating modes: Standard, Fibertom, LITT and LPS. The 5100 contain several other modes of operation that are not available on the Medilas D.

The Medilas D and the 5100 laser has a cooling system which includes an air-cooled, temperature controlled internal closed circuit water system.

Both the Medilas D and the 5100 laser are based on a single shutter with two parallel running microprocessors. Whenever one microprocessor runs differently from the other, the 5100 laser hardware initiates a "system fault" routine. During any "system fault," laser production and release immediately halt.

The Medilas D is not an Nd:YAG laser. The Medilas D is a diode laser. The comparison to the laser medium (diode) for the second predicate, Indigo's 830e (K955758) is to provide information to establish the Medilas D substantial equivalency determination in today's marketplace.

The Dornier Medilas D laser has the same principles of operation and similar technological characteristics as the previously cleared predicates, Dornier 5100 (K964760) and Indigo's 830e (K955758). As explained above, the minor differences in the aiming beam, software controlled operating modes, do not present new issues of safety or effectiveness.

From a clinical perspective and comparing design specifications, the Dornier Medilas D laser and the predicate devices are substantially equivalent and have the same intended use. 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 D and the predicate devices, Dornier 5100 and Indigo's 830e lasers.

Dornier Surgical Products, Inc. believes the minor differences of the Dornier Medilas D 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.



SEP 14 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Carol Wernecke
Dornier Surgical Products, Inc.
10027 South 51st Street
Phoenix, Arizona 85044

Re: K982629
Trade Name: Dornier Medilas D Laser
Regulatory Class: II
Product Code: GEX
Dated: July 27, 1998
Received: July 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 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.

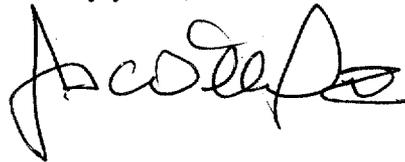
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,



h 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: K982629

Device Name: Dornier Medilas D Laser

Indications for Use:

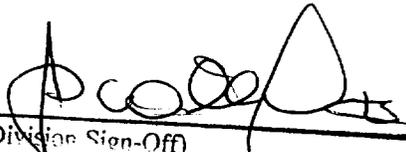
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The Dornier Medilas D is indicated for use in medicine and surgery, in the following medical specialties:

- ◆ Urology
- ◆ Plastic Surgery
- ◆ General Surgery
- ◆ Dermatology
- ◆ Gynecology
- ◆ Pulmonary Surgery
- ◆ Gastroenterology
- ◆ ENT
- ◆ Radiology

_____ 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 K982629