

JUL 20 1998

K981438



**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
Dornier Surgical Products, Inc.'s Medilas E 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 E 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: Schwartz Electro-Optics, Inc. CRL 2940 Erbium CR Laser (K971404 / K974039); Sharplan Model 4020 Erbium YAG Laser (K971648).

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

Dornier Surgical Products, Inc.	Phone: 770-426-1315
10027 South 51 <sup>st</sup> Street	Facsimile: 770-514-6288
Phoenix, AZ 85044	
Contact Person: Carol Wernecke	Date Prepared: April 3, 1998

**Name of Device and Name/Address of Sponsor**

Dornier Medilas E Laser  
Dornier Surgical Products, Inc.  
10027 South 51<sup>st</sup> Street  
Phoenix, AZ 85044

**Classification Name**

ER:YAG lasers have not been specifically classified by FDA.

**Predicate Devices**

Schwartz Electro-Optics, Inc. CRL2940 Erbium CR Laser (K971404 / K974039);  
Sharplan Model 4020 Erbium YAG Laser (K971648).

**Intended Use**

The Dornier Medilas E Laser is intended to be used in small and large joint arthroscopy, laparoscopic procedures, general and all surgical procedures for incision/excision, vaporization, ablation, and coagulation of soft tissue and cartilage. All soft tissues encountered in all surgical procedures are included in this indication such as, skin, cutaneous tissue, subcutaneous tissue, stratified

and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The Dornier Medilas E may also be used for skin resurfacing. The Dornier Medilas E is indicated for use in medicine and surgery, in the following medical specialties: Dermatology, Plastic Surgery, General Surgery, Urology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT, Thoracic Surgery, Oral & Maxillofacial Surgery, Ophthalmology & Podiatry.

#### **Technological Characteristics and Substantial Equivalence**

From a clinical perspective and comparing design specifications, the Dornier Medilas E 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 E and the predicate devices, SEO CRL 2940 Erbium CrystaLase and the Sharplan Model 4020 Erbium YAG laser.

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



JUL 20 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K981438  
Trade Name: Dornier Medilas E Laser  
Regulatory Class: II  
Product Code: GEX  
Dated: April 3, 1998  
Received: April 21, 1998

Dear Ms. Wernecke:

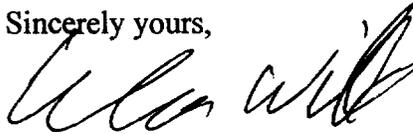
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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: K981438

Device Name: Dornier Medilas E Laser

**Indications for Use:**

The Dornier Medilas E Laser is intended to be used in small and large joint arthroscopy, laparoscopic procedures, general and all surgical procedures for incision/excision, vaporization, ablation, and coagulation of soft tissue and cartilage. All soft tissues encountered in all surgical procedures are included in this indication such as, skin, cutaneous tissue, subcutaneous tissue, stratified and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The Dornier Medilas E may also be used for skin resurfacing.

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

- ◆ Dermatology
- ◆ Plastic Surgery
- ◆ General Surgery
- ◆ Urology
- ◆ Gynecology
- ◆ Pulmonary Surgery
- ◆ Gastroenterology
- ◆ ENT
- ◆ Thoracic Surgery
- ◆ Oral & Maxillofacial Surgery
- ◆ Ophthalmology
- ◆ Podiatry

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

or

Over-the-Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K 981438