OCT 2 5 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Dornier Diode Laser Family

K020339

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 Diode Lasers is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device which includes the following: Diomed 810 nm Surgical Lasers as well as the Dornier diode lasers themselves, Dornier *Medilas D* Laser System (K982629), Dornier *Medilas D SkinPulse* Laser System (K000072) and Dornier *Medilas D SkinPulse S* Laser System (K003993).

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

Dornier MedTech America, Inc.
1155 Roberts Boulevard
Kennesaw, GA 30144
Contact Person: Tim Thomas

Phone: 770-514-6163
Facsimile: 770-514-6288

Date Prepared: October 21, 2002

Name of Device and Name/Address of Sponsor

Dornier's Diode Laser Family, including:

- *Medilas D* Laser System ("*Medilas D*")
- *Medilas D SkinPulse* Laser System ("*SkinPulse*")
- *Medilas D SkinPulse S* Laser System ("*SkinPulse S*")

Dornier MedTech America, Inc.
1155 Roberts Boulevard
Kennesaw, GA 30144

Classification Name

Diode lasers have not been specifically classified by FDA.

Predicate Devices

- Diomed 810 nm Surgical Lasers (K012398)
- Dornier *Medilas D* Laser System (K982629)
- Dornier *Medilas D SkinPulse* Laser System (K000072)
- Dornier *Medilas D SkinPulse S* Laser System (K003993)

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Intended Use

Dornier MedTech America, Inc. is requesting the expansion of the indications for use for the Dornier Diode Laser family previously cleared under K982629, K000072, K003993 and K021724. The Dornier Diode Laser family, *Medilas™ D Fibertom* Laser ("*Medilas D*"), *Medilas™ D SkinPulse™* ("*SkinPulse*") and *Medilas™ D SkinPulse™ S* ("*SkinPulse S*"), are intended for use in the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 28-85cc and 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 a handpiece). The *SkinPulse™* and *SkinPulse™ S* lasers are also for use for the treatment and/or removal of vascular lesions (tumors) and for the removal of unwanted hair.

The Dornier Diode Family Lasers are indicated for use in medicine and surgery, in the following medical specialties: Urology, Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT and Radiology.

This premarket notification requests clearance for the additional indication as stated:

The Dornier diode family lasers, *Medilas D Fibertom* Laser ("*Medilas D*"), *Medilas D SkinPulse* ("*SkinPulse*") and *Medilas D SkinPulse S* ("*SkinPulse S*") are intended for use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

Technological Characteristics and Substantial Equivalence

From a clinical perspective and comparing design specifications, the Dornier diode lasers and the predicate device, Diomed 810 nm Surgical Lasers are substantially equivalent. Based on the technological characteristics and overall performance of the devices, Dornier MedTech America, Inc. believes that no significant differences exist between the Dornier diode lasers and the predicate device.

Dornier believes the minor differences of the Dornier diode family lasers 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

OCT 2 5 2002

Dornier Medtech America, Inc.
Tim Thomas
Director, Regulatory, Quality & Clinical
1155 Roberts Boulevard
Kennesaw, Georgia 30144

Re: K020339
Trade/Device Name: Dornier Diode Laser Systems (Medilas D, Medilas D SkinPulse, Medilas D SkinPulse S)
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 21, 2002
Received: August 23, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Miriam C. Provost

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

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: K020339

Device Name: **Dornier's Diode Laser Family**

- ***Medilas D Fibertom* Laser System**
- ***Medilas D SkinPulse* Laser System**
- ***Medilas D SkinPulse S* Laser System**

Indications for Use:

Dornier MedTech America, Inc. is requesting the expansion of the indications for use for the Dornier Diode Laser family previously cleared under K982629, K000072, K003993 and K021724. The Dornier Diode Laser family, *Medilas™ D Fibertom* Laser ("*Medilas D*"), *Medilas™ D Skinulse™* ("*SkinPulse*") and *Medilas™ D SkinPulse™ S* ("*SkinPulse S*"), are intended for use in the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 28-85cc and 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 a handpiece). The *SkinPulse™* and *SkinPulse™ S* lasers are also for use for the treatment and/or removal of vascular lesions (tumors) and for the removal of unwanted hair.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Over-the-Counter Use _____

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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