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

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 Laser Family is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device which includes the following: Indigo 830e LaserOptic Treatment System with Diffuser-Tip™ Fiberoptic as well as the Dornier Diode Lasers themselves, Dornier *Medilas™ D Fibertom* Laser System (K982629), Dornier *Medilas™ D SkinPulse™* Laser System (K000072) and Dornier *Medilas™ D SkinPulse™ S* Laser System (K003993).

1. **Submitter's Name, Address, Telephone Number, Contact Person and Dat Prepared**

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

   Contact Person: Tim Thomas
   Directory, Regulatory, Quality, & Clinical

   Telephone number: 770-514-6163
   Facsimile number: 770-514-6288

   Date Prepared: May 23, 2002

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

   Classification Name: Diode lasers have not been specifically classified by FDA.

   Proprietary Name(s): Dornier's Diode Laser Family, including:
   - *Medilas™ D Fibertom* Laser System ("*Medilas D*")
   - *Medilas™ D SkinPulse™* Laser System ("*SkinPulse*")
   - *Medilas™ D SkinPulse™ S* Laser System ("*SkinPulse S*")

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

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3. Predicate Devices

- Indigo 830e LaserOptic Treatment System with Diffuser-Tip™ Fiberoptic (K963969)
- Dornier *Medilas™ D Fibertom* Laser System (K982629)
- Dornier *Medilas™ D SkinPulse™* Laser System (K000072)
- Dornier *Medilas™ D SkinPulse™ S* Laser System (K003993)

4. Indications for Use

The Dornier Diode Laser family is intended for the same use as previously cleared under *Medilas™ D Fibertom* Laser (K982629), *Medilas™ D SkinPulse™* Laser (K000072) and *Medilas™ D SkinPulse™ S* (K003993).

This premarket notification requests clearance for the expanded Indications for Use that will read as stated:

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.

5. Description of Technological Characteristics and Substantial Equivalence

From a clinical perspective and comparing design specifications, the Dornier Diode family lasers and the predicate device, Indigo 830e LaserOptic Treatment System with Diffuser-Tip™ Fiberoptic are substantially equivalent.

An analysis of equivalence has been conducted according to the "510(k) Substantial Equivalence Decision-Making Process" flowchart from the Blue Book Memorandum #86-3 and included as an attachment to this notification. 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.

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Dornier believes the minor differences of the Dornier diode family lasers and its predicate laser device 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

AUG 1 9 2002

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

Re: K021724
Trade/Device Name: Dornier Diode Laser Family
Medilas™ D Fibertom Laser System ("Medilas D")
Medilas™ D SkinPulse™ Laser System ("SkinPulse")
Medilas™ D SkinPulse™ S Laser System ("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: May 23, 2002
Received: May 24, 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 setforth 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.Page 2 – Mr. Tim Thomas

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,

for Mark N. Melkerson

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: K021724

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 Dornier *Medilas™ D Fibertom* Laser K982629, *Medilas™ D SkinPulse™* Laser K000072 and *Medilas™ D SkinPulse™ S* K003993 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.

This premarket notification requests clearance for the expanded Indications for Use that will read as stated:

The Dornier Diode Laser family, *Medilas™ D Fibertom* Laser ("*Medilas D*"), *Medilas™ D SkinPulse™* ("*SkinPulse*") and *Medilas D SkinPulse™ S* ("*SkinPulse S*"), with *ITT* Light Guide or Light Guide with bare fiber (fiber diameter 400µm or 600µm) 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.

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 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Prescription Use ✓ or Over-the-Counter Use

510(k) Number K021724