K 022544 1 OF 3

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Dornier *Medilas™ H* Laser Fiber Cables

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™ H* Laser Fiber Cables are based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device which is the SlimLine Fibers in 365, 550 and 1,000 micron sizes included in the Lumenis Modified Coherent VersaPulse Dual Wavelength Surgical Lasers and Delivery Accessories 510(k) #K980685

1. **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
   Directory, Regulatory, Quality, & Clinical

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

   Date Prepared: July 12, 2002

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

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

   Proprietary Name(s): Dornier *Medilas™ H* Laser Fiber Cables

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

3. Predicate Device

SlimLine Fibers in 365, 550 and 1,000 micron sizes included in the Lumenis Modified Coherent VersaPulse Dual Wavelength Surgical Lasers and Delivery Accessories 510(k) #K980685

4. Indications for Use

The Dornier *Medilas™ H* Laser Fiber Cables used in this premarket notification are the same accessory devices as in the previously cleared Dornier *Medilas™ H* Laser System under 510(k) #K984591 and maintain the same previously cleared indications for use as stated below.

The Dornier *Medilas™ H* 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* Laser is indicated for use in medicine and surgery, in the following specialties: Urology, Pulmonology, Arthroscopy, Lithotripsy, Gastroenterology, Gynecology, ENT, and General Surgery.

5. Description of Technological Characteristics and Substantial Equivalence

From a clinical perspective and comparing design specifications, the Dornier *Medilas™ H* Laser Fiber Cables and the predicate device, SlimLine Fibers in 365, 550 and 1,000 micron sizes included in the Lumenis Modified Coherent VersaPulse Dual Wavelength Surgical Lasers and Delivery Accessories clearance, 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 *Medilas™ H* Laser Fiber Cables and the predicate device.

Dornier believes the minor differences of the Dornier *Medilas™ H* Laser Fiber Cables 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 21 2002

Mr. Tim Thomas
Director, Regulatory, Quality and Clinical
Dornier MedTech America, Inc.
1155 Roberts Boulevard
Kennesaw, Georgia 30144

Re: K022544
Trade/Device Name: Dornier *Medilas™ H* Laser Fiber Cables
Regulation Number: 21CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 30, 2002
Received: August 1, 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" (21CFR 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: K022544

Device Name: **Dornier's *Medilas*™ *H* Laser Fiber Cables**

Indications for Use:

Dornier MedTech America, Inc. is requesting that the modified Dornier *Medilas*™ Laser Fiber Cables previously cleared as an accessory under Dornier *Medilas*™ *H* Laser Systems as 510(k) K984591, maintain the same indications for use. The modified and currently marketed Dornier *Medilas*™ Laser Fiber Cables will have the following indications for use.

The Dornier *Medilas*™*H 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* Laser is indicated for use in medicine and surgery, in the following specialties: Urology, Pulmonology, Arthroscopy, Lithotripsy, Gastroenterology, Gynecology, ENT, and General Surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

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

510(k) Number K022544

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

510(k) Number _____