MAY 3 0 2002

K020673

ATTACHMENT 6 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Wave Form Manufacturing Prolase General Shaped Fiber

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

Wave Form Manufacturing, Inc.
8095 SW Nimbus Ave, Bldg. 12
Beaverton, Oregon 97008
Contact: Charles R. Watkins

Phone: 800-332-8749
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Date Prepared: February 28, 2002

Name of Device and Name/Address of Sponsor

Trade Name: Wave Form Manufacturing Prolase General Shaped Fiber
Classification Name: Laser Surgical Instrument Accessories

Predicate Devices

InnovaQuartz General Shaped Fiber (K954904), single use
InnovaQuartz General Shaped Fiber (K994010), reuse
Dornier Medilas H Fibers (K001243)
Lumenis Slimline Fibers (K990947)

Device Description
The Wave Form Manufacturing Prolase General Shaped (PGS) Fiber is a fiber optic laser delivery system consisting of a 3 meter long silica fiber, clad in fluorinated doped silica, buffered with a fluorinated acrylate and a shaped tip. As an integral part of a laser system, the PGS fiber may be used for a wide variety of surgical procedures.

Indications for Use
The Wave Form Manufacturing Prolase General Shaped Fiber is intended to be used for vaporization, cutting, ablation and coagulation of soft tissue in conjunction with or without endoscopic equipment including laparoscopes, hysteroscopes, ureteroscopes, bronchoscopes, cystoscopes, gastroscopes, arthroscopes, colonoscopes, or for open surgery in contact or non-contact surgery with or without handpieces for use in coagulation, incision/excision, ablation and vaporization of soft tissue.

The Wave Form Manufacturing PGS Fiber is indicated for use in medicine and surgery in the following specialties: Urology, Pulmonology, Arthroscopy, Podiatry, Orthopedics, Lithotripsy, ENT Surgery, Neurosurgery, Gastroenterology, Plastic Surgery, Dermatology, Radiology, Gynecology, and General and Vascular Surgery.

Technological Characteristics and Performance Data

Design changes made to the Wave Form Manufacturing PGS Fiber are the addition of an internal proprietary quartz sleeve reflector which protects the laser focusing lens from back splatter of vaporized metal from the connector ferrule and the addition of an optical secondary memory cladding to help guide a steerable endoscope with the optical fiber.

Bench testing was performed to demonstrate that the device will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wave Form Manufacturing, Inc.
c/o Mr. Joe Brown
Optical Integrity
8317 Front Beach Road
Panama City Beach, FL 32407

MAY 3 0 2002

Re: K020673
Trade/Device Name: Wave Form Manufacturing Prolase General Shaped Fibers
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 28, 2002
Received: March 1, 2002

Dear Mr. Brown:

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,

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: 020673

Device Name: Wave Form Manufacturing Prolase General Shaped Fibers

Indications for Use:

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The Wave Form Manufacturing Prolase General Shaped Fiber is indicated for use in medicine and surgery in the following medical specialties:

- Urology
- Plastic Surgery
- Radiology
- Dermatology
- Pulmonolgy
- Gastroenterology
- Gynecology
- ENT
- Lithotripsy
- General and Vascular Surgery
- Arthroscopy
- Podiatry
- Orthopedics
- Neurosurgery
- Plastic Surgery

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use X

Or

Over-the-Counter Use _____

Miriam C. Provost

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

510(k) Number K020673