JUN - 5 1997

K965180

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: MyriadLase, Inc.
1315 FM 1187
Mansfield, Texas 76063
817-477-2041

Contact Person: Dr. Royice Everett

Date of Preparation: April 18, 1997

II. DEVICE NAME

Proprietary Name: StrâteFire™ Reusable Optical Fibers

Common Name: Reusable Laser Fiber

Classification Name: Fiberoptic Laser Delivery System

III. PREDICATE DEVICES

SideFire™ - Tipped Optical Fibers, MyriadLase, Inc.; K920553
SideFire™ - Tipped Reusable Optical Fibers, MyriadLase, Inc.; K952733
Laserguide Surgi Light Optical Fibers, Surgimedics; K914396

IV. DEVICE DESCRIPTION

The StrâteFire™ Reusable Optical Fiber is a fiberoptic laser energy delivery system intended for use with any surgical laser equipment fitted with SMA-905 compatible connectors and designed to operate at wavelengths between 532 and 1400 nm.

The StrâteFire™ Reusable Optical Fiber consists of a 400, 600, 800 or 1,000 micron diameter fused silica optical fiber with a proximal SMA-905 connector for attaching to a medical laser. Fibers are supplied sterile in heat-sealed Tyvek and may be reused after cleaning and sterilization as directed in the labeling.

V. INTENDED USE

Ablation and hemostasis in the treatment of gynecological and urological conditions, as well as multiple applications in gastroenterology and general surgery.

VI. COMPARISON TO PREDICATE DEVICES

The StrâteFire™ Reusable Optical Fibers are similar in design, and identical in function and intended use, to other laser optical fibers, such as the MyriadLase SideFire™ - Tipped Optical Fibers (K920553) and SideFire™ - Tipped Reusable Optical Fibers (K952733), and Surgimedics Laserguide® Surgi Light Optical Fibers,

(K914396). Optical performance testing has demonstrated comparable performance of the to the SideFire™ - Tipped Optical Fiber.

Accordingly, MyriadLase, Inc., concluded that the StrâteFire™ Reusable Optical Fibers are safe and effective for their intended use and perform at least as well as legally marketed predicate devices, such as the SideFire™ - Tipped Optical Fibers, SideFire™ - Tipped Reusable Optical Fibers, and Surgimedics Laserguide® Surgi Light Optical Fibers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 1997

MyriadLase, Inc.
c/o Mr. Richard A. Hamer
Richard Hamer Associates, Inc.
PO Box 16598
Ft. Worth, Texas 76162-0958

Re: K965180
Trade Name: Stratefire™ Reusable Optical Fibers
Regulatory Class: II
Product Code: GEX
Dated: April 18, 1997
Received: April 21, 1997

Dear Mr. Hamer:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

510(k) Number (if known): K965180

Device Name: ~~StraightFire™~~ STRATEFIRE Reusable Optical Fibers

Indications for Use:

Ablation and hemostasis in treatment of gynecological and urological conditions, as well as multiple applications in gastroenterology and general surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K965180

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number

Prescription Use X (Per 21 CFR 801.109) OR Over-the-Counter Use _____

(Optional Format 1-2-96)