SECTION 5
510(k) SUMMARY (CONT.)

510(k) Notification K K100746

GENERAL INFORMATION

Applicant:
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343
U.S.A.
Phone: 952-930-6000
Fax: 952-930-6007

JUN 11 2010

Contact Person:
Darlene Crockett-Billig
President
Experien Group, LLC
155-A Moffett Park Drive, Suite 210
Sunnyvale, CA 94089
U.S.A.
Phone: 408-400-0856
Fax: 408-400-0865
Email: dcb@experiengroup.com

Date Prepared: March 15, 2010

DEVICE INFORMATION

Fiber One is a fiber optic delivery device that is supplied as a sterile, single-use device. Fiber One is intended for use with the GreenLight XPS Laser System for its FDA cleared indications for use. It can access the tissue in multiple planes. Fiber One is a liquid cooled delivery device which enables the delivery of up to 180W of power and aids in maintaining a clear environment at the fiber cap.

Classification:
21 CFR§878.4810

Product Code:
GEX

Trade Name:
Fiber One

Generic/Common Name:
Laser surgical instrument for use in general and plastic surgery and in dermatology

SECTION 5
510(k) SUMMARY (CONT.)

PREDICATE DEVICE

Fiber One is substantially equivalent to the 2090 Fiber (K062719). The 2090 Fiber is a fiber optic delivery device that was cleared as an accessory with the GreenLight HPS Surgical Laser System & Accessories (K062719) that is currently being used with the GreenLight XPS Laser System (K092735).

INTENDED USE

Fiber One features a side firing mechanism delivering up to 180W of 532nm light to tissue. Fiber One can be used for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Fiber One will deliver 532nm laser energy from a compatible laser console (GreenLight XPS Laser System) to tissue during surgical procedures, including photoselective vaporization of the prostate for benign prostatic hyperplasia (BPH).

INDICATIONS FOR USE

Fiber One is a fiber optic delivery device intended for use with the GreenLight™ XPS Laser System for its FDA cleared indications for use.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for Fiber One are substantially equivalent to the indications for use of the predicate device. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Therefore, the Fiber One is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench and animal testing was conducted on Fiber One to support a determination of substantial equivalence to the predicate device.

SUMMARY

Fiber One is substantially equivalent to the predicate device, the 2090 Fiber (K062719).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

American Medical Systems, Inc.
% Experien Group, LLC
Ms. Darlene Crockett-Billig
President
155-A Moffett Park Drive, Suite 210
Sunnyvale, California 94089

JUN 11 2010

Re: K100746
Trade/Device Name: Fiber One
Regulation Number: 21 CFR 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 13, 2010
Received: May 14, 2010

Dear Ms. Crockett-Billig:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100746

Device Name: Fiber One

Indications For Use:
Fiber One is a fiber optic delivery device intended for use with the GreenLight™ XPS Laser System for its FDA cleared indications for use.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P. Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100746