JUN 15 2012

**SECTION 7**
**510(K) SUMMARY [21 CFR 807.92]**

## 510(k) Notification K120870

**SUBMITTER'S NAME AND ADDRESS**
Doreen Nakamura
Senior Regulatory Affairs Specialist
American Medical Systems
Innovation Center – Silicon Valley
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San Jose, CA 95134
U.S.A.
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Email: Doreen.Nakamura@AmericanMedicalSystems.com

**DATE SUMMARY WAS PREPARED**
June 14, 2012

**DEVICE TRADE/PROPRIETARY NAME**
GreenLight MoXy™ Fiber Optic

**DEVICE COMMON/ USUAL NAMES**
Laser surgical instrument for use in general and plastic surgery and in dermatology

**DEVICE CLASSIFICATION NAMES**
Powered Laser Surgical Instrument

**PRODUCT CODE**
GEX

**CLASSIFICATION**
Class II- 21 CFR§878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology

**PREDICATE DEVICE**
Fiber One (K100746) cleared June 11, 2010.

## SECTION 7
## 510(K) SUMMARY [21 CFR 807.92]

### DEVICE INFORMATION

Model Number 0010-2400 is supplied as a single-use, sterile product and is compatible with the GreenLight™ XPS Laser System. It can access the tissue in multiple planes. Model Number 0010-2400 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.

### INTENDED USE

The Model Number 0010-2400 features a side firing mechanism delivering up to 180W of 532nm light to tissue. Model Number 0010-2400 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.

Model Number 0010-2400 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

Model Number 0010-2400 is a fiber optic delivery device intended for use with the GreenLight™XPS Laser System for its FDA cleared indications for use.

### SUMMARY OF TECHNOLOGICAL CHARACTERISTICS TO THE PREDICATE DEVICE

The Model Number 0010-2400 modification is deemed equivalent and there are no changes to the device intended use and/or device functional scientific technology.

| | Model 0010-2400 | Fiber One |
|---|---|---|
| **510(k) Number** | K120870 | K100746 |
| **Regulation Number** | 21 CFR§878.4810 | 21 CFR§878.4810 |
| **Regulation Name** | Laser surgical instrument for use in general and plastic surgery and in dermatology | Laser surgical instrument for use in general and plastic surgery and in dermatology |
| **Classification** | Class II | Class II |
| **Product Code** | GEX | GEX |

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## 510(K) SUMMARY [21 CFR 807.92]

| | Model 0010-2400 | Fiber One |
|---|---|---|
| **Laser System Compatibility** | GreenLight XPS Laser System | GreenLight XPS Laser System |
| **Endoscope/Cystoscope Compatibility** | 22 to 24 Fr continuous flow | 22 to 24 Fr continuous flow |
| **Saline flow** | ≥0.3mL/sec | ≥0.3mL/sec |
| **Fiber and Cap Assembly Outer Diameter** | ≤2.3 mm | ≤2.3 mm |
| **Total Length** | 305cm | 305cm |
| **Operation Length** | 36cm | 36cm |
| **Fiber Core Size** | 750µm | 750µm |
| **Internal Fiber Cooling** | Yes | Yes |
| **Max. Laser Power** | 180W | 180W |
| ***Energy Limit*** | *650kJ* | *400kJ* |
| **Beam Area at 2 mm** | 0.48mm$^2$ | 0.48mm$^2$ |
| **Power Density at 2 mm** | @ 180W = 326W/mm$^2$<br>@120W = 218W/mm$^2$ | @ 180W = 326W/mm$^2$<br>@120W = 218W/mm$^2$ |
| **Materials** | 304 stainless steel, polyamide, silica glass | 304 stainless steel, polyamide, silica glass |
| **Sterilization** | Ethylene Oxide | Ethylene Oxide |
| **Dating*** | 2 years, accelerated | 2 years, accelerated |
| **Storage Conditions** | 4 to 40 °C, keep dry | 4 to 40 °C, keep dry |
| **Metal Cap*** | Minor tolerance refinements to increase process capability | Initial design |
| **Labeling, IFU*** | Clarifications to instructions, use and improved caution statements, 2 additional languages added | Released at Rev B |

*denotes post-510k changes that did not trigger a new 510k submission.

### SUMMARY OF NON-CLINICAL TESTING
All necessary bench testing was conducted on the Model Number 0010-2400 to support a determination of substantial equivalence to the predicate device.

### SUBSTANTIAL EQUIVALENCE
The Model Number 0010-2400 uses the same surgical procedures and is targeted for the same patient population as the predicate device. The proposed indications for use for

## SECTION 7
## 510(K) SUMMARY [21 CFR 807.92]

Model Number 0010-2400 are equivalent to the indications for use/intended use, identical sterilization, and materials of the predicate device. There are no differences in the technological characteristics between the devices, nor does the change raise any new issues of safety or efficacy. Therefore, the Model Number 0010-2400 is substantially equivalent to the predicate device.

### CONCLUSION

AMS considers Model Number 0010-2400 to be substantially equivalent to the Fiber One (K100746).

### MANUFACTURING FACILITY

American Medical Systems
3070 Orchard Drive
San Jose, CA 95134
Establishment Registration Number: 2937094

### STERILIZATION FACILITY

Sterigenics US LLC
4900 Gifford Avenue
Los Angeles, CA 90058
Establishment Registration Number: 2011171

## STERILIZATION

The modification to Model Number 0010-2400 did not affect sterilization.

The following ETO residue values were extracted from the original 510k for Fiber One (MoXy) K100746, Appendix 3: Sterilization, page 12 of 15, Table 6.

TABLE 6. Total Extracted Residues (mg/device)

| UNIT NUMBER | SAMPLE ID | EO | ECH |
|---|---|---|---|
| 1 | Day 1, A | 2.10 | 1.10 |
| 2 | Day 1, B | 2.57 | 1.16 |
| 3 | Day 1, C | 2.16 | 1.47 |
| 4 | Day 2, A | 1.18 | 0.509 |
| 5 | Day 2, B | 1.32 | 0.201 |
| 6 | Day 2, C | 1.11 | 1.11 |
| 7 | Day 3, A | 0.702 | 1.05 |
| 8 | Day 3, B | 0.653 | 1.02 |
| 9 | Day 3, C | 0.571 | 0.807 |

Model 0010-2400 is the same as Fiber One device and uses the same sterilization cycle and meets the ISO 10993-7:2008 recommendations for limited exposure values for EO <4 mg/device and ECH <9 mg/device.

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

JUN 15 2012

American Medical Systems
% Ms. Doreen Nakamura
Senior Regulatory Affairs Specialist
3070 Orchard Drive
San Jose, California 95134

Re: K120870
Trade/Device Name: Model Number 0010-2400- for use with GreenLight XPS Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 16, 2012
Received: May 17, 2012

Dear Ms. Nakamura:

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.

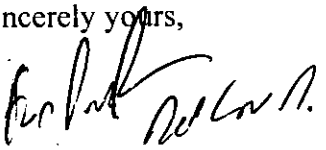
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 6**
**STATEMENT OF INDICATIONS FOR USE**

**510(k) Number:** K120870

**Device Name:** Model Number 0010-2400

**Indications for Use:**

Model Number 0010-2400 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)

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

510(k) Number K120870