DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 20, 2014

American Medical Systems
Mr. Josh Clarin
Regulatory Affairs Manager
3070 Orchard Drive
San Jose, California 95134

Re: K140679
Trade/Device Name: SureFlex Lithotripsy Laser Fibers
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: June 5, 2014
Received: June 6, 2014

Dear Ms. Clarin:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140679

Device Name
SureFlex Lithotripsy Laser Fibers

Indications for Use *(Describe)*
General
SureFlex laser fibers are intended for use in laser-based surgical applications, including, but not limited to endoscopic, laparoscopic and open surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection and incision of soft and cartilaginous tissue and surgical procedures involving vaporization, ablation and fragmentation of calculi (urinary and biliary).
SureFlex is designed primarily for holmium (Ho:YAG) lasers, but may be used with any laser wavelength between 500nm and 2200nm that has been cleared for surgical use, e.g. Nd:YAG, KTP, Alexandrite, Argon, Ruby, Diode
Specific, by Surgical Specialty (most common use first)
Urology -
Urinary Lithotripsy including but not limited to endoscopic and laparoscopic fragmentation, ablation and vaporization of urinary calculi found from the lower pole of the kidney to the urethra and distal impacted fragments of steinstrasse.
Urological Surgery (vaporization, coagulation, hemostasis, excision and incision of soft tissue) including, but not limited to open, endoscopic and laparoscopic surgery for the removal of superficial and invasive bladder tumors and lesions, including condylomas, treatment of ureteral strictures obstructions, polyps, vascularities and hemangioma as well as prostatectomy (BPH).
Gastroenterology -
Laser-based surgical procedures including, but not limited to open, endoscopic and laparoscopic gastroenterological surgery for ablation, vaporization, fragmentation, coagulation, hemostasis, incision, excision, resection, and hemostasis of biliary calculi, lesions, neoplasms, polyps, ulcers, tears, erosions and tumors.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.06.19 14:58:18 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
As required by 21CFR 807.92(c)

510(k) Number: K140679

Date Prepared: February 10, 2014

Submitter Information:

Submitter's Name/
Address:

American Medical Systems
3070 Orchard Drive
San Jose,CA 95134

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Device Information:

Trade Name/Proprietary Name:	SureFlex™ Lithotripsy Laser Fibers
Common Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification:	21 CFR § 878.4810
Product Code:	GEX

Predicate Device:

SureFlex™ Lithotripsy Laser Fibers K050108

Device Description:

The SureFlex™ Lithotripsy Laser Fiber (SureFlex fiber) is a fiber optic laser delivery device consisting of a patented, high energy termination (Black Hole™); a length of silica/silica fiber with a UV cured polymer secondary cladding and an ethylene tetrafluoro-ethylene copolymer (ETFE) jacket. The standard fiber output is a laser polished tip. SureFlex fibers are designed for use in a wide variety of surgical procedures as an integral part of a surgical laser system.

510(k) Summary
As required by 21CFR 807.92(c)

The device is identical to the currently marketed predicate device, SureFlex fiber, with the exception of the modification to the resin for the flouroacrylate resin material and a labeling update changing the listed maximum power of the 200 µm fiber from 25W to 12W. There are no other changes to device design, material or Indications for Use.

Indications for Use:

General

SureFlex laser fibers are intended for use in laser-based surgical applications, including, but not limited to endoscopic, laparoscopic and open surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection and incision of soft and cartilaginous tissue and surgical procedures involving vaporization, ablation and fragmentation of calculi (urinary and biliary). SureFlex is designed primarily for holmium (Ho:YAG) lasers, but may be used with any laser wavelength between 500nm and 2200nm that has been cleared for surgical use, e.g. Nd:YAG, KTP, Alexandrite, Argon, Ruby, Diode

Specific, by Surgical Specialty (most common use first)

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510(k) Summary
As required by 21CFR 807.92(c)

Comparison to the Predicate Device:

The fundamental scientific technology on the SureFlex™ laser fiber is unchanged from the predicate device. The intended use and indication for use are also the same as the predicate device. In addition, the subject SureFlex laser fibers utilize the same surgical approach and targeted patient population as the predicate devices (K050108). The primary change to the device is a new resin for the flouracrylate polymer cladding material and maximum power listed in the IFU from 25W to 12W for the 200 μm fiber size.

Summary of Non-Clinical Testing:

Bench testing was performed to support this submission. Results of the testing demonstrate that the SureFlex Laser Fibers meet product specification and performance requirements.

The following testing has been successfully completed:

- Shelf Life
- Biocompatibility
- Performance Testing (Bench): Active Bending Test

Clinical Testing:

No clinical testing was performed to support this Traditional 510(k) Premarket Application.

Statement of Equivalence:

The SureFlex fibers have the same indications for use and fundamental scientific technology as the predicate device. Based on this and the design and engineering data provided in the pre-market notification, the SureFlex fibers have been shown to be substantially equivalent.