JUN 28 2012

510(k) SUMMARY

Fiberoptic Fabrications Inc.'s
Fiberoptic Laser Delivery System

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

Fiberoptic Fabrications, Inc.
495 Main Street
Wilbraham, MA 01095
Phone: (413) 374-4303
Facsimile: (413) 599-1640

Contact Person: Carol J.Morello,VMD

Date Prepared: June 5, 2012

Name of Device and Name/Address of Sponsor

Fiberoptic Fabrications Fiber optic Laser Delivery System

Fiberoptic Fabrications, Inc.
495 Main Street
Wilbraham, MA 01095

Common or Usual Name

Fiber optic laser delivery system

Classification Name

Surgical laser accessory

Predicate Devices

CeramOptec, Inc MegaBeam Fiber Optic Laser Delivery Systems (K934008,K943445,K943444,K943526,K943527,K941909)
Biolitec Radial Emitting shaped fiber optic delivery system (K110080).

Intended Use / Indications for Use

The fiber optic laser delivery system is intended for delivery of laser light to soft tissue in the contact and non-contact mode during surgical procedures, including via endoscopes. The fiber optic laser delivery system is intended for use with any cleared surgical laser with an SMA 905 or SMA 905 compatible connector It is indicated for use in general surgical applications for: incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in a contact or non contact mode. It is also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated. It is also indicated for use in lithotripsy with a compatible laser cleared for the desired application. It is indicated for use with Argon, KTP/532, Ho:YAG, Nd:YAG,1.44YAG, and Diode Lasers (635-1900nm) with peak and continuous power from 1-200W. Core size 230um- 45W, 365um- 113W, 400um-135W, 600um- 200W, 800um-200W, and 1000um-200W.

Technical Characteristics

The fiber optic laser delivery system contains the same components and design as the already cleared CeramOptec MegaBeam optical fibers and the Biolitec radial emitting shaped fiber optic delivery system.. The optical fiber is composed of quartz fiber core with a coaxially mounted protective sheath. The fibers distal tip can be several configurations and the fiber can be used with handpieces. This is industry standard for delivery systems thus no questions of safety or efficacy are raised.

Performance Data

The performance of the fiber optic laser delivery systems is well established and documented so no performance testing is included. The fiber optic delivery systems operates in the same manner as the predicate devices and performs with no difference as compared with the predicate devices.

Substantial Equivalence

The Fiberoptic Fabrications fiber optic laser delivery systems are as safe and effective for the indications for use as the CeramOptec fiber optic laser delivery systems and the Biolitec radial emitting shaped fiber optic delivery system previously cleared thus the Fiberoptic Fabrications fiber optic laser delivery systems are substantially equivalent.

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FIBEROPTIC FABRICATIONS, INC.'S
FIBER OPTIC LASER DELIVERY SYSTEMS
SUBSTANTIAL EQUIVALENCE CHART

	Fiberoptic Fabrications	CeramOptec MegaBeam fiber optic laser delivery systems K934008,K943445,K943444,K943526,K943527.K941909	Biolitec radial emitting shaped fiber optic delivery K110080
Intended Use	Intended Use: The fiber optic laser delivery system is intended for delivery of laser light to soft tissue in the contact and non-contact mode during surgical procedures, including via endoscopes. The fiber optic laser delivery system is intended for use with any cleared surgical laser with an SMA 905 or SMA 905 compatible connector	The fiber optic laser delivery system is intended for delivery of laser light to soft tissue in the contact and non-contact mode during surgical procedures, including via endoscopes. The fiber optic laser delivery system is intended for use with any surgical laser with an SMA 905 compatible connector.	The fiber optic laser delivery system is intended for delivery of laser light to soft tissue in the contact and non-contact mode during surgical procedures, including via endoscopes. The fiber optic laser delivery system is intended for use with any surgical laser with an SMA 905 compatible connector.

	Fiberoptic Fabrications	CeramOptec MegaBeam fiber optic laser delivery systems K934008,K943445,K943444,K943526,K943527.K941909	Biolitec radial emitting shaped fiber optic delivery K110080
Indications for Use	It is indicated for use in general surgical applications for: incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in a contact or non contact mode. It is also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated. It is also indicated for use in lithotripsy with a compatible laser cleared for the desired application. It is indicated for use with Argon, KTP/532, Ho:YAG, Nd:YAG,1.44YAG, and Diode Lasers (635-1900nm) with peak and continuous power from 1-200W.	It is indicated for use in general surgical applications for : incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, cardiothoracic surgery, dental applications, endovenous occlusion of the greater saphenous vein, laser assisted lipolysis, and benign prostatic hyperplasia with a compatible laser cleared for use in the desired applications. It is also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated. It is also indicated for use in lithotripsy with a compatible laser cleared for the desired application	It is indicated for use in general surgical applications for : incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, cardiothoracic surgery, dental applications, endovenous occlusion of the greater saphenous vein, laser assisted lipolysis, and benign prostatic hyperplasia with a compatible laser cleared for use in the desired applications. It is also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated.

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	Fiberoptic Fabrications	CeramOptec MegaBeam fiber optic laser delivery systems K934008,K943445,K943444,K943526,K943527.K941909	Biolitec radial emitting shaped fiber optic delivery K110080
Delivery Systems			
Fiber	Flexible fiber	Flexible fiber	Flexible fiber
Material	Quartz glass	Quartz glass	Quartz glass
Core diameter	200- 1000um	200 - 1000um	600
Proximal end	SMA 905 connector or SMA 905	SMA 905 connector	SMA 905 connector
Sterile	compatible connector Sterile	HGM connector or other Sterile	HGM or other Sterile
Distal End	Shaped fibers, side fibers, hand pieces. Shaped fibers include:flat,orb, cone, chisel, or radial.	Shaped fibers, side fibers, hand pieces. Shaped fibers include:flat,orb, cone,or chisel	Side fibers
Max Recommended Power	Core size: 230um 45W 365um 113W 400um 135W 600um 200W 800um 200W 1000um 200W	Up to 25W N/A N/A 200W 200W 200W	Up to 25W N/A N/A 200W 200W 200W

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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 28 2012

Fiberoptic Fabrications, Incorporated
% Ms. Carol J. Morello, VMD
495 Main Street
Wilbraham, Massachusetts 01095

Re: K120810
Trade/Device Name: Fiber optic laser delivery system
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 28, 2012
Received: June 05, 2012

Dear Ms. Morello:

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.

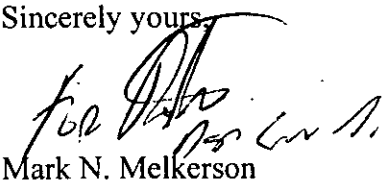
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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

Indications for Use Statement

510(k) Number (if known): K120810

Device Name: Fiber optic laser delivery system

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Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 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

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