K082928

OCT 1 6 2008

Boston Scientific Corporation

510(k) Summary for Straight Fire Holmium Laser Fiber

A. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

Lauren B. Anderson
Specialist, Regulatory Affairs
508-683-4707
or
Donna Gardner
Director, Regulatory Affairs
508-683-4398

C. Device Name

Trade name: To Be Determined
*Although the Trade Name is to be determined, for purposes of this submission the proposed device will be referred to as the Straight Fire Holmium Laser Fiber
Common/usual name: Laser Instrument, Surgical, Powered
Classification Name: GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology
21 CFR 878.4810, Class II

D. Predicate Device(s)

Trade name: AccuFlex™ Laser Lithotripsy Fibers
Common/usual name: Laser Instrument, Surgical, Powered
Classification Name: GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology
21 CFR 878.4810, Class II
Premarket Notification: InnovaQuartz, Inc., K050108

and

Trade name: SlimLineEZ™ Fiber Device
Common/usual name: Laser Instrument, Surgical, Powered
Classification Name: GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology
21 CFR 878.4810, Class II
Premarket Notification: Lumenis, K011703

E. Device Description

The Straight Fire Holmium Laser Fiber is a fiber optic laser energy delivery device consisting of a silica core fiber jacketed with ethelylene tetraflouroethylene (ETFE) and a SMA 905 connector. It is equipped with a polished, flat output tip. This fiber may be used in a variety of laser based surgical cases as an integral part of laser systems.

For use with Ho:YAG laser systems with a standard SMA 905 connector that have been cleared for surgical use. Recommended Ho:YAG lasers are Dornier and New Star.

F. Intended Use

The Straight Fire Holmium Laser Fiber is intended for use in laser-based surgical applications, including, but not limited to endoscopic, laparascopic and open surgical procedures involving vaporization, ablation and fragmentation of calculi (urinary and biliary) and surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection and incision of soft and cartilaginous tissue.

The Straight Fire Holmium Laser Fiber is designed for use with holmium (Ho:YAG) lasers with a standard SMA 905 connector that have been cleared for surgical use.

G. Technological Characteristics

The Straight Fire Holmium Laser Fiber has the same technological characteristics (i.e. SMA 905 connector, length of fiber optic cable, and strain relief) as the predicate devices.

H. Substantial Equivalence

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" a direct comparison of key characteristics demonstrates that the proposed laser fiber is substantially equivalent to the predicate device in terms of intended use, technological characteristics, and performance characteristics. The Straight Fire Holmium Laser Fiber is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 6 2008

Boston Scientific Corporation
% Intertek Testing Services
Kachi C. Enyinna
Staff Engineer – Medical Devices
2307 East Aurora Road
Twinsburg, Ohio 44087

Re: K082928
Trade/Device Name: Undetermined
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 30, 2008
Received: October 1, 2008

Dear Kachi Enyinna:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); good manufacturing practice requirements as set

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Boston Scientific Corporation

Indications for Use Statement

510(k) Number (if Known): K082928

Device Name: Undetermined

Indications For Use:

The Straight Fire Holmium Laser Fiber is indicated for use in laser-based surgical applications, including, but not limited to endoscopic, laparascopic and open surgical procedures involving vaporization, ablation and fragmentation of calculi (urinary and biliary) and surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection and incision of soft and cartilaginous tissue.

The Straight Fire Holmium Laser Fiber is designed for use with holmium (Ho:YAG) lasers with a standard SMA-905 connector that have been cleared for surgical use.

Prescription Use X (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 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 General, Restorative, and Neurological Devices

510(k) Number K082928

Traditional 510(k)
Straight Fire Holmium Laser Fiber
August 25, 2008