MAR 29 2011

510(k) Summary for Flexiva TracTip Laser Fiber

A. Sponsor

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

B. Contact

Lauren Anderson
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or

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Manager, Regulatory Affairs
508-683-4175
riekn@bsci.com

C. Device Name

Trade name: Flexiva™ TracTip
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: Flexiva™ (Modified Straight Fire 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
Premarket Notification: Boston Scientific, K100078

E. Device Description

The Flexiva TracTip Laser Fibers are fiber optic laser energy delivery devices consisting of a SMA-905 connector, strain relief, and a silica core fiber jacketed with ethylene tetrafluoroethylene (ETFE). The Flexiva TracTip fibers are equipped with a polished and reinforced ball-shaped output tip. These fibers may be used in a variety of laser-based surgical cases as an integral part of laser systems.

For use with Ho:YAG and Nd:YAG laser systems with a standard SMA-905 connector that have been cleared for surgical use. Recommended for use with Lumenis manufactured Ho:YAG and Nd:YAG lasers. Please refer to the laser

system User Manual for complete information regarding applications, contraindications, precautions and warnings.

F. Intended Use

The Flexiva TracTip Laser Fibers are designed for use with Ho:YAG and Nd:YAG lasers for indications that are cleared for these laser systems, including, but not limited to endoscopic, laparoscopic, and open surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection, incision of soft and cartilaginous tissue, and fragmentation of urinary and biliary calculi (Ho:YAG wavelength only). The fiber is designed for use with a standard SMA-905 connector that have been cleared for surgical use.

G. Technological Characteristics

The Flexiva TracTip Laser Fiber has the same technological characteristics (i.e. SMA 905 connector, length of fiber optic cable, and strain relief) as the predicate device. It is equipped with a polished and reinforced ball-shaped output tip, whereas the predicate device has a polished flat tip.

H. Substantial Equivalence

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 Flexiva TracTip Laser Fiber is as safe, as effective, and performs as well as the predicate device.

I. Performance Testing (Bench and User Evaluation)

Boston Scientific has conducted performance testing with samples aged at T=0 and T=13 months accelerated aging in support of the distal ball tip design change. The following testing was completed to evaluate the effects of the design change:

- Tip Fracture Resistance
- Scope Testing
- Power Rating/Output Efficiency Testing
- Aiming Beam Testing

The results of the performance testing demonstrate equivalence of the Flexiva TracTip to the predicate Flexiva laser fibers. The Flexiva TracTip fibers are considered safe and effective for their intended use.

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

Boston Scientific Corporation
Urology and Women's Health Division
% Ms. Lauren Anderson
100 Boston Scientific Way, M21
Marlborough, Massachusetts 01752

MAR 29 2011

Re: K110685
Trade/Device Name: Flexiva™ TracTip Laser Fiber
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: March 24, 2011
Received: March 25, 2011

Dear Ms. Anderson:

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.

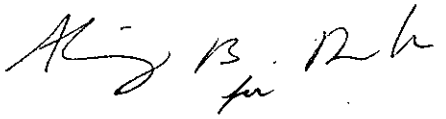
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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	To be determined.
Device Name	Flexiva™ TracTip Laser Fiber
Indications For Use	The Flexiva™ TracTip Laser Fibers are designed for use with Ho:YAG and Nd:YAG lasers for indications that are cleared for these laser systems, including, but not limited to endoscopic, laparoscopic, and open surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection, incision of soft and cartilaginous tissue, and fragmentation of urinary and biliary calculi (Ho:YAG wavelength only). The fiber is designed for use with a standard SMA-905 connector that have been cleared for surgical use.

Prescription Use __X____ AND/OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110685