April 28, 2021

Boston Scientific
% Dave Yungvirt, CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K210925
Trade/Device Name: Flexiva Pulse Laser Fiber, Flexiva Pulse Tractip Laser Fiber, Flexiva Pulse ID Laser Fiber, Flexiva Pulse ID 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: II
Product Code: GEX
Dated: March 24, 2021
Received: March 29, 2021

Dear Dave Yungvirt:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino, M.S.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210925

Device Name
Flexiva Pulse Laser Fiber; Flexiva Pulse TracTip Laser Fiber
Flexiva Pulse ID Laser Fiber; Flexiva Pulse ID TracTip Laser Fiber

Indications for Use *(Describe)*
Flexiva Pulse and Flexiva Pulse TracTip laser fibers are intended to be used as a device that transmits Ho:YAG laser energy from cleared laser consoles to urological anatomy. Flexiva Pulse and Flexiva Pulse TracTip laser fibers are indicated for urologic applications for which the laser systems are cleared, limited to endoscopic procedures involving vaporization, ablation, hemostasis, coagulation, excision, resection, incision of soft tissue, and lithotripsy of urinary calculi. The fiber is designed for use with a standard SMA-905 connector and has been cleared for surgical use.

Flexiva Pulse ID and Flexiva Pulse ID TracTip laser fibers are intended to be used as a device that transmits Ho:YAG laser energy from cleared laser consoles to urological anatomy. Flexiva Pulse ID and Flexiva Pulse ID TracTip laser fibers are indicated for urologic applications for which the laser systems are cleared, limited to endoscopic procedures involving vaporization, ablation, hemostasis, coagulation, excision, resection, incision of soft tissue, and lithotripsy of urinary calculi. The fiber is designed for use with a standard SMA-905 connector and has been cleared for surgical use.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510K SUMMARY

510(k) Summary for the Flexiva Pulse Laser Fiber, Flexiva Pulse TracTip Laser Fiber, Flexiva Pulse ID Laser Fiber, and Flexiva Pulse ID TracTip Laser Fiber

A. Date Prepared

April 26, 2021

B. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01752

C. Contact

Rebecca Perrine
Sr. Regulatory Affairs Specialist
508-683-4604
rebecca.perrine@bsci.com

or

John Capone
Regulatory Affairs Director
617-842-9632
john.capone@bsci.com

D. Proposed Device

Trade Name(s):	Flexiva Pulse Laser Fiber Flexiva Pulse TracTip Laser Fiber Flexiva Pulse ID Laser Fiber Flexiva Pulse ID TracTip Laser Fiber
Common/Usual Name:	Laser Instrument, Surgical, Powered
Classification Number:	21 CFR 878.4810
Classification Name:	Laser Surgical Instrument for use in general and plastic surgery and in dermatology
Classification:	Class II
Product Code:	GEX
Product Code Name:	Powered Laser Surgical Instrument
510(k) Number:	K210925

510K SUMMARY

E. Predicate Devices

Trade Name:	Flexiva™ High Power Single Use Laser Fiber
Common/Usual Name:	Laser Instrument, Surgical, Powered
Classification Number:	21 CFR 878.4810
Classification Name:	Laser Surgical Instrument for use in general and plastic surgery and in dermatology
Classification:	Class II
Product Code:	GEX
Product Code Name:	Powered Laser Surgical Instrument
Identification of Predicate Device:	Modified Straight Fire Laser Fiber, Boston Scientific, K100078

Trade Name:	Flexiva™ TracTip Single Use Laser Fiber
Common/Usual Name:	Laser Instrument, Surgical, Powered
Classification Number:	21 CFR 878.4810
Classification Name:	Laser Surgical Instrument for use in general and plastic surgery and in dermatology
Classification:	Class II
Product Code:	GEX
Product Code Name:	Powered Laser Surgical Instrument
Identification of Predicate Device:	Flexiva™ TracTip™ Single Use Laser Fiber, Boston Scientific, K110685

F. Device Description

The Flexiva Pulse Laser Fiber, Flexiva Pulse TracTip Laser Fiber, Flexiva Pulse ID Laser Fiber, and Flexiva Pulse ID TracTip Laser Fiber are fiber optic laser energy delivery devices consisting of a SMA connector (Black Hole design), and an ETFE jacketed silica core fiber. The Flexiva Pulse and Flexiva Pulse ID fibers are equipped with a polished, flat output tip (242µm, 365µm, 550µm and 910µm size) and the Flexiva Pulse TracTip and Flexiva Pulse ID TracTip fibers are equipped with a polished and reinforced ball-shaped output tip (242µm size).

These fibers may be used in a variety of laser-based surgical cases. For the Flexiva Pulse ID and the Flexiva Pulse ID TracTip laser fibers, an RFID (radio-frequency identification) tag enables read/write data storage for compatible RFID-equipped laser systems (closed systems).

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G. Intended Use/Indications for Use

Flexiva Pulse and Flexiva Pulse TracTip laser fibers are intended to be used as a device that transmits Ho:YAG laser energy from cleared laser consoles to urological anatomy. Flexiva Pulse and Flexiva Pulse TracTip laser fibers are indicated for urologic applications for which the laser systems are cleared, limited to endoscopic procedures involving vaporization, ablation, hemostasis, coagulation, excision, resection, incision of soft tissue, and lithotripsy of urinary calculi. The fiber is designed for use with a standard SMA-905 connector and has been cleared for surgical use.

Flexiva Pulse ID and Flexiva Pulse ID TracTip laser fibers are intended to be used as a device that transmits Ho:YAG laser energy from cleared laser consoles to urological anatomy. Flexiva Pulse ID and Flexiva Pulse ID TracTip laser fibers are indicated for urologic applications for which the laser systems are cleared, limited to endoscopic procedures involving vaporization, ablation, hemostasis, coagulation, excision, resection, incision of soft tissue, and lithotripsy of urinary calculi. The fiber is designed for use with a standard SMA-905 connector and has been cleared for surgical use.

H. Technological Characteristics Compared to Predicate

The principles of operation are identical between the predicate and subject devices. The Flexiva Pulse, Flexiva Pulse TracTip, Flexiva Pulse ID, and Flexiva Pulse ID TracTip laser fibers have the same technological characteristics and fundamentals design as the predicate devices.

The differences between the subject device and the predicates are minor. Differences include:

- Use with holmium lasers only with an increased maximum frequency
- Connector/hub including: manufacturing, shape and non-patient contacting connector/hub materials
- Primary and Secondary Coating on fiber length

The technological characteristics remain equivalent to the predicate device because the modifications that are the subject of this submission are limited to improvements to the existing design.

I. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the Flexiva Pulse Laser Fiber, Flexiva Pulse TracTip Laser Fiber, Flexiva Pulse ID Laser Fiber, and Flexiva Pulse ID TracTip Laser Fiber are substantially equivalent to the predicate devices in terms of intended use, technological characteristics and performance characteristics. The Flexiva Pulse Laser Fiber, Flexiva Pulse TracTip Laser Fiber, Flexiva Pulse ID Laser Fiber, and Flexiva Pulse ID TracTip Laser Fiber are as safe and effective as the predicate devices.

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J. Biocompatibility

Biocompatibility testing was performed to show that all patient contacting materials meet applicable biocompatibility standards per **ISO 10993-1:2018** and the FDA guidance: Use of International Standard **ISO 10993-1** "*Biological evaluation of medical devices. Evaluation and testing within a risk management process*."

The following testing was performed with passing results to support the biocompatibility of the device:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Materials Mediated Pyrogenicity

K. Performance Testing (Bench Evaluation)

Boston Scientific has conducted performance testing with samples aged at T=0 and T= 3 year accelerated aging in support of the proposed laser device. IEC 60601-1:2005 was considered when testing connector temperature. The Flexiva Pulse, Flexiva Pulse TracTip, Flexiva Pulse ID, and Flexiva Pulse ID TracTip laser fibers conform to Section 11.1.1, Maximum temperature during Normal Use. All other sections of IEC 60601-1 Clause 11 are not applicable, as the fiber functions only as an accessory to the Medical Electrical Equipment (laser).

The following testing was completed to evaluate the effects of the design changes.

- Fiber Jacket Outer Diameter
- No Damage to Scope Liner (Ball-Tip)
- Ball Tip Fracture Resistance
- Distal Tip Length
- Fiber Length
- Bent Transmission
- Fiber Stiffness
- Fiber Power Rating and Power Output Efficiency of Fiber
- Fiber Connector Temperature and Durability
- Fiber Aiming Beam Visualization
- Laser Compatibility

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- RFID Recognition
- Scope Adaptor Compatibility
- Tensile Strength of fiber to connector housing
- Fiber Hub to Connector Housing Torque
- Pouch Seal Integrity
- Pouch Seal Strength
- Biocompatibility

The results of the performance testing demonstrate that the Flexiva Pulse Laser Fiber, Flexiva PulseTracTip Laser Fiber, Flexiva Pulse ID Laser Fiber, and Flexiva Pulse ID TracTip Laser Fiber are considered safe and effective for their intended use.