July 9, 2025

Boston Scientific Corporation
Galit Gershon
Senior Regulatory Affairs Specialist
100 Boston Scientific Way - Urology Division
Marlborough, Massachusetts 01752

Re: K251759
Trade/Device Name: Flexiva Pulse Laser Fiber; Flexiva Pulse TracTip Laser Fiber; Pulse ID Laser Fiber; Flexiva Pulse ID TracTip 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: II
Product Code: GEX
Dated: June 8, 2025
Received: June 9, 2025

Dear Galit Gershon:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251759

Device Name

Flexiva Pulse Laser Fiber; Flexiva Pulse TracTip Laser Fiber; Flexiva Pulse ID Laser Fiber; Flexiva Pulse ID TracTip Laser Fibers

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.

510(k) Summary for Flexiva Pulse/ ID Laser Fiber

Date Prepared: 08-June-2025

A. Submitter

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B. Contacts

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C. Device Name

Trade Name	Flexiva Pulse Laser Fiber; Flexiva Pulse TracTip Laser Fiber; Flexiva Pulse ID Laser Fiber; Flexiva Pulse ID TracTip Laser Fibers
Common Name	Laser Instrument, Surgical, Powered
Classification	Class II per 21 CFR 878.4810
Classification Name	Laser Surgical Instrument for use in general and plastic surgery and in dermatology
Product Code	GEX
Product Code Name	Powered Laser Surgical Instrument

D. Predicate Devices

For the purposes of establishing substantial equivalence, the designs and technological characteristics of the proposed Flexiva Pulse/ ID Laser Fiber were compared to the following 510(k)-cleared device.

Table 11-1: Predicate Device for Establishing Substantial Equivalence

Characteristics	Predicate Device
Device Trade Name	Flexiva Pulse Laser Fiber, Flexiva Pulse TracTip Laser Fiber, Flexiva Pulse ID Laser Fiber, Flexiva Pulse ID TracTip Laser Fiber
Classification Name	Laser Surgical Instrument for use in general and plastic surgery and in dermatology

Regulation Number	21 CFR 878.4810
Classification	Class II
Product Code	GEX
510(k) Submitter/ Holder	Boston Scientific Corporation
510(k) Clearance Number & Date	K210925 Cleared 28-April -2021

E. Device Description

Flexiva Pulse, Flexiva Pulse TracTip, Flexiva Pulse ID and Flexiva Pulse ID TracTip Single Use Laser Fibers are fiber optic laser energy delivery devices consisting of a SMA connector (Black Hole design), and an ETFE jacketed silica core fiber. 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 Flexiva Pulse ID laser fibers, an RFID (Radio-frequency identification) tag enables read/write data storage for compatible RFID-equipped laser systems (closed systems).

F. Intended Use/Indication 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.

G. Principles of Operation

The operating principle for the Flexiva Pulse/ ID Laser Fiber (submitted under K210925) remains unchanged.

Flexiva Pulse/ ID Laser Fibers deliver holmium (Ho:YAG) laser energy endoscopically from a laser console to soft tissues or urinary calculi. The energy travels within the fiber's glass core and exits through the distal end of the fiber. Upon impact, the holmium energy fragments urinary calculi and/or ablates soft tissue.

H. Comparison of Key Technological/Performance Characteristics

The proposed Flexiva Pulse/ ID Laser Fiber have the same technological characteristics and fundamental design as the predicate Flexiva Pulse/ ID Laser Fiber (K210925).

Table 11-2: Flexiva Pulse/ ID Laser Fiber Comparison and Substantial Equivalence

Characteristics	Predicate Flexiva Pulse/ ID Laser Fiber (K210925)	Proposed Flexiva Pulse/ ID Laser Fiber	Similarities / Differences
Indication for Use	**Flexiva Pulse and Flexiva Pulse TracTip Lase Fiber:** 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 Fiber:** 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.	**Flexiva Pulse and Flexiva Pulse TracTip Lase Fiber:** 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 Fiber:** 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.	Identical
Reusability	Single Use	Single Use	Identical
Flexiva Pulse/ ID Laser Fiber is Supplied	Sterile	Sterile	Identical

Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Identical
Packaging	Tyvek pouch	Tyvek pouch	Identical
Sizes Offered (µm)	242, 365, 550, and 910 242 µm TracTip configuration	242, 365, 550, and 910 242 µm TracTip configuration	Identical
Overall Length	242 µm: 3 meters 365, 500, 910 µm: 2.6 meters	242 µm: 3 meters 365, 500, 910 µm: 2.6 meters	Identical

I. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the proposed Flexiva Pulse/ ID Laser Fibers are substantially equivalent to the predicate Flexiva Pulse/ ID Laser Fibers (K210925) in terms of intended use, technological characteristics, and performance characteristics. The proposed Flexiva Pulse/ ID Laser Fiber is as safe, as effective, and performs as well as the predicate devices (K210925).

J. Performance Testing

To evaluate the secondary coating resin material change introduced with the proposed Flexiva Pulse/ ID Laser Fiber, a Design Verification was executed to support the safe and effective use of the proposed Flexiva Pulse/ ID Laser Fiber. The new secondary coating resin was subjected to the following tests:

- Bent Transmission
- Fiber durability while firing
- Fiber connector temperature
- Laser System output accuracy

From a biocompatibility standpoint, the contact classification of the proposed Flexiva Pulse/ ID Laser Fiber is identical to the predicate Flexiva Pulse/ ID Laser Fiber (cleared under K210925). A biological evaluation assessment for the proposed Flexiva Pulse/ ID Laser Fiber was conducted and it was concluded there are no biocompatibility risks associated with the proposed Flexiva Pulse/ ID Laser Fiber.

K. Conclusion

Based on the intended use/indications for use, comparison of key technological characteristics, and performance testing presented in this premarket submission, it is concluded that the proposed Flexiva Pulse/ ID Laser Fibers are substantially equivalent to the predicate Flexiva Pulse/ ID Laser Fibers (cleared under K210925).