October 30, 2025

Boston Scientific Corporation
Brandon Burris
Sr Reg Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K252529
Trade/Device Name: Moses™ 200 D/F/L Laser Fiber (M0068130100); Moses™ 365 D/F/L Laser Fiber (M0068130110); Moses™ 550 D/F/L Laser Fiber (M0068130120)
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: August 6, 2025
Received: August 11, 2025

Dear Brandon Burris:

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.10.30 22:06:47 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252529 ?

Please provide the device trade name(s). ?

Moses™ 200 D/F/L Laser Fiber (M0068130100);
Moses™ 365 D/F/L Laser Fiber (M0068130110);
Moses™ 550 D/F/L Laser Fiber (M0068130120)

Please provide your Indications for Use below. ?

The Moses fibers are intended for use with compatible laser systems in surgical procedures involving endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue, and lithotripsy of calculi in the medical specialty of urology.

Please select the types of uses (select one or both, as applicable). ?

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K252529

Moses D/F/L Laser Fibers – 510(k) Summary

1. Submission Details

Date Prepared:
06 August, 2025

Sponsor:
Boston Scientific Corporation
Urology Division
300 Boston Scientific Way
Marlborough, MA 01752

Contact:
Brandon Burris
Sr. Regulatory Affairs Specialist
(859) 396-4674
Brandon.burris@bsci.com

Proposed Device:

Premarket Notification – Traditional 510(k)	
Device Common Name	Holmium Laser Fibers
Device Trade Name	Moses™ 200 D/F/L Laser Fiber (M0068130100); Moses™ 365 D/F/L Laser Fiber (M0068130110); Moses™ 550 D/F/L Laser Fiber (M0068130120)
Classification	Class II per 21 CFR §878.4810
Classification Name	Powered Laser Surgical Equipment
Product Code	GEX

Table 1: Scope of Submission

Predicate Device:

Premarket Notification – Predicate	
510(k) Clearance and Date	K170121, Cleared May 22, 2017
Device Trade Name	Lumenis Family of Holmium Surgical Lasers and Delivery Devices and Accessories
Classification	Class II per 21 CFR §878.4810
Classification Name	Powered Laser Surgical Equipment
Product Code	GEX

Table 2: Predicate Device

2. Device Description

The Moses D/F/L Laser Fibers are single-use, straight-firing delivery devices that transfer laser energy from the laser console to the treatment site. The laser energy travels within the fiber's silica glass core and exits through the distal end of the fiber. The Moses 200 D/F/L Fiber consists of a Ball Tip which aids in the passability of the small core fiber through a deflected flexible endoscope. Moses 365 D/F/L and Moses 550 D/F/L Fibers have a flat distal tip. The Moses Fibers also include an embedded RFID Chip, allowing the Laser Console to recognize fibers and limits the fibers to a single use. The Moses fibers are available in a single, box-one configurations. The Moses fibers are compatible with the (Lumenis) Pulse 120 Laser System,

used for the energy delivery of the Holmium Laser Energy (Ho:YAG) from the Console. All Moses fibers have a 3-year shelf life and are provided EtO Sterilized.

The Principles of Operation of the proposed Moses D/F/L Fibers remain unchanged from the predicate Moses Fibers included in K170121 (Lumenis Family of Holmium Surgical Lasers and Delivery Devices and Accessories).

3. Intended Use/Indications for Use

The Moses fibers are intended for use with compatible laser systems in surgical procedures involving endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue, and for lithotripsy.

4. Comparison to Predicate Device

The proposed Moses Fibers have the same technological characteristics and fundamental design as the legally marketed predicate Moses Fibers (K170121).

Subject Device Intended Use	Predicate Device (K170121) Intended Use
The Moses fibers are intended for use with compatible laser systems in surgical procedures involving endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue, and for lithotripsy.	Intended for use in surgical procedures involving *open, laparoscopic* and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: urology; urinary lithotripsy; *arthroscopy; discectomy; E.N.T. surgery; gynecological surgery; pulmonary surgery; gastroenterology surgery; dermatology and plastic surgery and general surgery*

While the Intended Use is not exactly the same, the proposed intended use of the Moses Fibers is a reduced scope from the predicate devices. The predicate intended use includes all proposed intended uses. The Product Code, Class, Environment Use, and Users are the same.

Additionally, the following characteristics were assessed to be the same or similar:

- Principles of Operation
- Dimensions
- General Design Features
- User Interface
- Sterility
- Nature of Patient Contact and Patient-Contacting Materials

The differences in technological characteristics have been assessed and do not raise any new questions of safety or effectiveness. The proposed changes to Packaging and Shelf Life were assessed through Performance Bench Testing, utilizing acceptable methods to evaluate the differences, and does not introduce new safety concerns that would impact the device's intended use or substantial equivalence. This evaluation demonstrates that the Moses D/F/L Laser Fibers are substantially equivalent to the predicate device (K170121).

5. Performance Testing

The Moses Fibers have undergone Performance Testing in the following ways:

Biocompatibility Testing		
Assessment of the safety of the patient contacting materials of the Moses Fibers		
Cytotoxicity	Irritation	Sensitization
Acute Systemic Toxicity	Material Mediated Pyrogenicity	
Performance – Bench Testing		

Assessment of the Moses Fibers and their packaging materials at the T=0 and T=37 month accelerated aging timepoints, to demonstrate safety and effectivity of the Moses Fibers over the proposed 3 year Shelf-Life		
Fiber to Connector Tensile Strength	Fiber Tip Damage	Scope Liner Damage (Ball Tip fiber only)
Fiber Distal Tip Length	Fiber Jacket Outer Diameter	Fiber Overall Length
Transmission Efficiency	Minimum Bend Radius	Durability
Fiber Connector Temperature	Aiming Beam Visibility	Connector RFID Transponder Content
Console Compatibility	Fiber Tip Renewal	Pouch Seal Peel Strength
Pouch Integrity	Product Protection	Aseptic Presentation of Sterile Barrier System
Label Adhesion and Print Quality	Device 2x Sterilization	Shelf Life
Challenge Sterilization		
Performance – Usability Testing		
Assessment of the new Mounting Card introduced to the Moses Fibers		
Summative Usability Evaluation		

The testing performed concludes that the Moses Fibers perform both safely and effectively per their design requirements and does not introduce new safety concerns that would impact the device's intended use or substantial equivalence.

6. Conclusion

Based on the intended use, comparison of key technological characteristics, and performance testing presented in this premarket submission, it is concluded that the proposed Moses D/F/L Laser Fibers are substantially equivalent to the predicate Moses Fibers (cleared under K170121) and that the proposed changes (Packaging and Shelf-Life) do not introduce new safety concerns that would impact the device's intended use or substantial equivalence.