May 18, 2026

Boston Scientific Corporation
Ilana Sahnovsky
Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K260100
Trade/Device Name: MOSES Raydar™
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: January 13, 2026
Received: April 16, 2026

Dear Ilana Sahnovsky:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 R. Kreitz -S

for Mark J. Antonino, M.S.
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

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.	K260100

Please provide the device trade name(s).

MOSES Raydar™

Please provide your Indications for Use below.

The MOSES Raydar™ system with delivery fibers and accessories are indicated for use in the performance of specific surgical applications in Urology as follows:

• Endoscopic transurethral incision of the prostate (TUIP), bladder neck incision of the prostate (BNI), holmium laser ablation of the prostate (HoLAP), holmium laser enucleation of the prostate (HoLEP), hemostasis, vaporization, and excision for treatment of benign prostatic hyperplasia (BPH).
• Endoscopic urological surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including treatment of:
o Bladder
o Bladder, urethral and ureteral tumors
o Ureteral strictures
• Urinary Lithotripsy including:
o Endoscopic fragmentation of urinary (urethral, ureteral, bladder and renal) calculi, including cystine, calcium oxalate, monohydrate, and calcium oxalate dihydrate stones.

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

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

510(k) Summary

A. Submitter Information:
Boston Scientific Corporation
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United States

Contact Person
Ilana Sahnovsky
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Boston Scientific Corporation
Urology Division
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B. Date of 510(k) summary preparation: April 16, 2026.

C. Subject Devices:

Trade Name	MOSES Raydar™
Common name	Holmium Surgical Laser
Regulation 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
Classification name	Powered Laser Surgical Instrument

D. Predicate Device:

Trade Name	Primary Predicate Device: Pulse™ 120H (P120H) Secondary Predicate Device: Lumenis Pulse™ 120H (LP120H)
Regulation 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 (Powered Laser Surgical Instrument)
510(k) submitter/holder	Boston Scientific Corporation
510(k)#	K170121

E. Device Description:
MOSES Raydar™ is a solid state, single wavelength, flash lamp pumped Holmium surgical laser system which emits laser radiation at a wavelength of 2.1µm.
This device provides utility in urology and is used with a variety of delivery fibers and accessories to deliver the Holmium laser energy in urological surgical applications.
MOSES Raydar™ Laser system is comprised of the following main components and features:

- Laser console
- Control screen
- Dual-pedal footswitch
- Aiming beam
- Optional fiber support arm

This device is operated and controlled via proprietary software. The proprietary software is embedded in the main and peripheral processors, as well as within the graphical user interface application in the processing unit.
The MOSES Raydar™ device incorporates the Raydar™ technology for lithotripsy procedures and provides a real-time fiber-target proximity measurement, displayed as a visual indication for the surgeon on the OR screen, alongside with the endoscopic image on the OR external screen.

F. Intended Use/Indications for Use:
MOSES Raydar™ system with delivery fibers and accessories are indicated for use in the performance of specific surgical applications in Urology as follows:

- Endoscopic transurethral incision of the prostate (TUIP), bladder neck incision of the prostate (BNI), holmium laser ablation of the prostate (HoLAP), holmium laser enucleation of the prostate (HoLEP), hemostasis, vaporization, and excision for treatment of benign prostatic hyperplasia (BPH).
- Endoscopic urological surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including treatment of:
    - Bladder
    - Bladder, urethral and ureteral tumors
    - Ureteral strictures
- Urinary Lithotripsy including:
    - Endoscopic fragmentation of urinary (urethral, ureteral, bladder and renal) calculi, including cystine, calcium oxalate, monohydrate, and calcium oxalate dihydrate stones.

G. Technological Characteristics Compared to the Predicate:
The fundamental Holmium laser technology, operating principles and performance remain unchanged for the MOSES Raydar™ device as compared to the predicate devices (K170121).
The following characteristics were assessed to be the same or similar:

- Principles of Operation for Holmium treatment
- Dimensions
- General Holmium laser design features

The differences in technological characteristics related to the new Raydar™ technology

include the following:

- Software and hardware changes that enable and control the new Raydar™ technology as well as support the presentation of the proximity indication on the external OR screen.
- Additional Graphical user interface (GUI) settings to support the proximity indication
- Slight reduction in the green aiming beam wavelength

Additional differences consist of the following:

- Modification of Holmium laser treatment parameter's specifications, including the change in the minimum value of the pulse duration range and the introduction of an extended frequency range (up to 120Hz).

These differences have been assessed, and it was confirmed that these modifications result in equivalent performance and risk relative to the predicate devices.

H. Performance Data:

Non-clinical performance testing included the following:

- Electromagnetic Compatibility (EMC): Assessed and tested per IEC 60601-1-2 and FDA guidance *Electromagnetic Compatibility (EMC) of Medical Devices*
- EMT (Electrical, Mechanical, Thermal) Safety: Assessed and tested per IEC 60601-1, IEC 60601-2-22, IEC 60825-1
- Software Verification and Validation: Validated and verified per IEC 62304 and General Principles of Software Validation; Final Guidance for Industry and FDA Staff
- Cybersecurity: Assessed and tested per FDA guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*
- Bench Testing (design verification):
  Non-Clinical Bench Testing was conducted in accordance with FDA guidance Recommended Content and Format of Non-Clinical Bench Performance Testing in Premarket Submissions to evaluate the Raydar™ proximity sensing technology incorporated into the subject device. Testing included assessment of proximity distance estimation accuracy, proximity indication latency, Raydar-related emergency stop functionality and additional verification of the supporting hardware and software changes.

I. Conclusion:

The comparison of device intended use and technological characteristics, as well as the non-clinical testing, support that the MOSES Raydar™ device performs as safely and effectively as the Pulse™ 120H and Lumenis Pulse™ 120H predicate devices and is therefore substantially equivalent.