February 10, 2026

Boston Scientific Corporation
Cassidy Yeomans
Regulatory Affairs Specialist
300 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K260119
Trade/Device Name: SpaceOAR Vue System (SV-2101)
Regulation Number: 21 CFR 892.5725
Regulation Name: Absorbable Perirectal Spacer
Regulatory Class: Class II
Product Code: OVB
Dated: January 14, 2026
Received: January 14, 2026

Dear Cassidy Yeomans:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
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. | K260119 |

Please provide the device trade name(s).

SpaceOAR Vue System (SV-2101)

Please provide your Indications for Use below.

SpaceOAR Vue System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR Vue System to reduce the radiation dose delivered to the anterior rectum.
The SpaceOAR Vue System is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

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 for SpaceOAR Vue System

## A Submitter

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
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## B Contact

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## C Subject Device

Trade Name: SpaceOAR Vue System (SV-2101)
Device Type: Absorbable Perirectal Spacer
Device Classification Name: Hydrogel Spacer
Device Classification: Class II per 21 CFR §892.5725
Product Code: OVB
Review Panel: Radiology
Identification of Subject Device: SpaceOAR Vue System, K260119

## D Predicate Device

Trade Name: SpaceOAR Vue System (SV-2101)
Device Type: Absorbable Perirectal Spacer
Device Classification Name: Hydrogel Spacer
Device Classification: Class II per 21 CFR §892.5725
Product Code: OVB
510(k) Submitter/Holder: Boston Scientific Corporation
Identification of Predicate Device: SpaceOAR Vue System, K182971

# E Device Description

The SpaceOAR Vue System consists of components for the preparation of an absorbable hydrogel spacer and a delivery mechanism packaged in a single use system. Upon injection, between the anterior rectal wall and prostate, the precursor (trilysine buffer solution with PEG-SG-TIB) and accelerator (a buffered solution) mix in the device Y-connector where the formation of SpaceOAR Vue hydrogel is initiated. The SpaceOAR Vue hydrogel is formed through cross-linking of the polyethylene glycol with succinimidyl glutarate and triiodobenzoate (PEG-SG-TIB) and Trilysine. This reaction gives off no measurable heat. The hydrogel temporarily positions the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR Vue System to reduce the radiation dose delivered to the anterior rectum. The hydrogel is biodegradable and maintains space for the entire course of prostate radiotherapy treatment. The hydrogel degrades via hydrolysis and is excreted via renal filtration.

# F Indications for Use

SpaceOAR Vue System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR Vue System to reduce the radiation dose delivered to the anterior rectum.

The SpaceOAR Vue System is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

The Indications for Use Statement for the proposed SpaceOAR Vue System is identical to the predicate device.

# G Technological Characteristics Compared to Predicate

The principles of operation and underlying technological characteristics of the proposed SpaceOAR Vue System and the predicate device are identical. Both devices are systems that facilitate implantation of 10cc PEG biodegradable hydrogel between the anterior rectal wall and prostate prior to radiotherapy. This temporarily creates space between the anterior rectal wall and prostate during radiotherapy. The PEG hydrogel is broken down through hydrolysis and excreted from the body through renal filtration. The differences between the subject device and the predicate are minor. Differences include changes to:

- The nominal pH of the accelerator solution
- The inner diameter of the hypotubes within the Y-connector
- The luer ring color of the Y-connector
- The shelf carton color

These differences have been assessed and do not raise any new questions of safety or effectiveness. This evaluation demonstrates that the SpaceOAR Vue System is substantially equivalent to the predicate device.

# H Performance Data

Applicable verification and validation testing was performed as required by the Boston Scientific design control process. The following performance data evaluated over the specified shelf life were provided in support of the substantial equivalence determination:

- Percent swell of hydrogel
- Hydrogel gelation time
- Hydrogel persistence
- Maximum force required to inject hydrogel
- Hydrogel performance after 60 minutes post precursor solution preparation
- Usability Testing

The predicate and subject device are predominantly identical in device design with limited changes to device components. A risk-based biocompatibility assessment of these limited changes indicates that no new biocompatibility testing is required to assess the proposed device change. The proposed SpaceOAR Vue System is biologically safe for its intended use.

The principles of operation and intended use are identical for both the predicate and proposed device. Verification and usability testing of the proposed device were completed and confirmed that the proposed SpaceOAR Vue System meets the same functional and performance specifications as the predicate SpaceOAR Vue System. The clinical workflow for device implantation is identical for both the predicate and proposed device. Therefore, clinical data were not required to support a determination of substantial equivalence.

The conclusion of the assessments demonstrates that the modified device continues to function as intended in a manner equivalent to the predicate device. The modified device raises no new issues of safety or effectiveness compared to the predicate.

# I Conclusion

Based on the performance data, the same principles of operation the same intended use, and same indications for use, the modified SpaceOAR Vue System is substantially equivalent to its predicate device, K182971.