



August 28, 2020

Boston Scientific Corporation  
% Ms. Jeanne O'Toole  
Principal Regulatory Affairs Specialist  
100 Boston Scientific Way  
MARLBOROUGH MA 01752

Re: K202224

Trade/Device Name: SpaceOAR System  
Regulation Number: 21 CFR 892.5725  
Regulation Name: Absorbable Perirectal Spacer  
Regulatory Class: Class II  
Product Code: OVB  
Dated: August 6, 2020  
Received: August 7, 2020

Dear Ms. O'Toole:

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/combo-products/guidance-regulatory-information/postmarketing-safety-reporting-combo-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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.  
Director  
Division of Radiological Health  
OHT7: Office of In Vitro Diagnostics  
and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K202224

Device Name

SpaceOAR System

Indications for Use (Describe)

SpaceOAR 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 System to reduce the radiation dose delivered to the anterior rectum.

The SpaceOAR 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.

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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**SECTION 5**

**510K SUMMARY**

**510(k) Summary for SpaceOAR Hydrogel System**

**A. Sponsor**

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

**B. Contact**

Jeanne O'Toole  
Principal Regulatory Affairs Specialist  
508-683-4271  
[jeanne.otoole@bsci.com](mailto:jeanne.otoole@bsci.com)

**C. Proposed Device**

Trade Name: SpaceOAR Hydrogel System, Model Number: SO-2101  
Common / Usual Name: Hydrogel Spacer  
Regulation Number: 892.5725  
Classification Name: Absorbable Perirectal Spacer  
Classification: Class II  
Product Code: OVB  
Review Panel: Radiology

**D. Predicate Device**

Trade Name: SpaceOAR Hydrogel System, Model Number: SO-2101  
Common / Usual Name: Hydrogel Spacer  
Regulation Number: 892.5725  
Classification Name: Absorbable Perirectal Spacer  
Classification: Class II  
Product Code: OVB  
Identification of Predicate Device: SpaceOAR Hydrogel System, K181465

**E. Device Description**

The SpaceOAR Hydrogel System consists of components for the preparation of a synthetic, absorbable hydrogel spacer and a delivery mechanism provided in a sterile, single use package. The SpaceOAR hydrogel is a synthetic, absorbable polyethylene glycol (PEG)-based hydrogel that upon injection creates a space that 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 the perirectal spacer to reduce the radiation dose delivered to the anterior rectum. SpaceOAR hydrogel is completely synthetic with no animal or human derived components. It is composed of biodegradable material and maintains space for the

entire course of prostate radiotherapy treatment (approximately 3 months) and is completely absorbed by the patient's body over time (approximately 6 months).

#### **F. Indications for Use**

SpaceOAR 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 System to reduce the radiation dose delivered to the anterior rectum. The SpaceOAR 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 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 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:

- The Bioset component is being replaced by an aluminum cap vial stopper, and vented vial adapter (VVA), that includes a hollow spike and a flange that enables the spike to be centered over the cap, and stopper.
- The 18g X 15cm needle hub is being modified to add a white colorant and a blue stamped marking to indicate needle bevel direction. There are no changes to the design specifications of the hub or needle.
- The system packaging tray is being modified to account for the change in components from the Bioset to the VVA. The tray material is unchanged.
- The outer pouch which acts as the sterile barrier is being modified. The bottom web material of the outer pouch has been changed from 48ga (0.48mil) PET layer and 200 Ga (2 ml) LDPE layer to 100 Ga (1ml) Biaxially Oriented Nylon/PE/COEX layer, 10# LDPE and 200 Ga (2 ml) Peelable Sealant. The top web Tyvek material is **identical** to that of the predicate device.
- The device labeling, including the instructions for use (IFU), is being modified to reflect system component changes.

The technological characteristics remain equivalent to the predicate device because the modifications that are the subject of this submission are limited to replacing the Bioset component, which has been discontinued by the manufacturer, as well as improvements to the existing design.

#### **H. Substantial Equivalence**

The modified SpaceOAR System is substantially equivalent to the predicate SpaceOAR System (K181465). It has the same intended use of creating a temporary space between the prostate and the rectum and the same indication for use. The system design and principles of operation remain the same.

### **I. Performance Data**

The modifications to the subject SpaceOAR System have been tested to ensure compliance to the initial specifications. Based on the change assessment including risk analysis, the design verification tests outlined below were repeated. The test methods used were the same as those submitted for the predicate device.

- Sterilization Validation
- Shelf Life Testing
- System Needle to Hub Tensile Strength
- Fluid Connection
- SpaceOAR Hydrogel System Prep and Assembly Time
- PEG Vial Puncture Force
- Packaging Performance Testing

The predicate and proposed device are predominantly identical in device design with limited changes to device components, packaging and labeling. 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 System is biologically safe for its intended use.

The principles of operation and underlying device technology are **identical** for both the predicate and proposed device. 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.

Verification and validation of the proposed device were completed and confirmed that the proposed SpaceOAR System meets the same functional and performance specifications as the predicate SpaceOAR System.

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.

### **J. Conclusion**

Based on the test data, the same intended use, and same indications for use, the modified SpaceOAR System is substantially equivalent to its predicate device, K181465.