September 26, 2025

Boston Scientific Corporation
Elena Hennessey
Regulatory Affairs Consultant
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K252921
Trade/Device Name: Radial Jaw™ 4 Pulmonary Biopsy Forceps
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: BWH
Dated: September 12, 2025
Received: September 12, 2025

Dear Elena Hennessey:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director, Respiratory Devices Team
DHT1C: Division of Sleep Disordered
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252921

Device Name
Radial Jaw™ 4 Pulmonary Biopsy Forceps

Indications for Use *(Describe)*
These single-use biopsy forceps are specifically designed to collect tissue endoscopically for histologic examination. These forceps should not be used for any purpose other than their intended function.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Radial Jaw™ 4 Pulmonary 510(k) Summary

1. **Submitter:**

Boston Scientific Corporation
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Date Prepared: September 24, 2025

2. **Proposed Device:**

Trade Name:	Radial Jaw™ 4 Pulmonary Biopsy Forceps
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	874.4680
Product Code:	BWH
Regulatory Class:	Class II

3. **Predicate Device:**

Trade Name:	Radial Jaw™ 4 Pulmonary Biopsy Forceps
Manufacturer:	Boston Scientific Corporation
510(k) Number:	K121186
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	874.4680
Product Code:	BWH
Regulatory Class:	Class II

4. **Device Description:**

The Radial Jaw™ 4 Pulmonary Biopsy Forceps (RJ4 Pulmonary) is a sterile, single-use device. The RJ4 Pulmonary Biopsy Forceps are available in two jaw sizes: RJ4 Pulmonary Large

Capacity is compatible with a 2.8 mm or larger working channel endoscope and the RJ4 Pulmonary Standard Capacity is compatible with a 2.0 mm or larger working channel endoscope. The RJ4 Pulmonary Large Capacity is only available without a needle. The RJ4 Pulmonary Standard Capacity is available with or without a needle. Both the RJ4 Pulmonary Large Capacity and Standard Capacity devices have a 100cm working length, and are offered in Box 5 and Box 20 packaging configurations.

To operate the device, the user slides the spool back and forth over the handle body to open and close the jaws. The spool simultaneously actuates the dual pull wires, each of which run the length of the device and terminate with a connection to the jaw. The dual pull wire design allows the jaws to pivot, thus enabling tissue acquisition with a tangential approach if desired. Using RJ4 Pulmonary Biopsy Forceps the user can obtain a tissue sample by opening the jaws, pressing the jaws against the biopsy site, closing the jaws, and pulling the jaws away from the biopsy site.

5. Intended Use / Indications for Use:

These single-use biopsy forceps are specifically designed to collect tissue endoscopically for histologic examination. These forceps should not be used for any purpose other than their intended function.

Proposed Contraindications:

- This procedure should not be attempted in any patient whose general medical condition and degree of respiratory failure would not allow the patient to tolerate bronchoscopy (rigid or flexible) and/or the manipulation required to perform the procedure.
- Patients with elevated bleeding times or uncorrectable coagulopathies.

6. Technological Characteristics:

The proposed Radial Jaw 4 Pulmonary Biopsy Forceps has the same technological characteristics as the currently cleared Radial Jaw™ 4 Pulmonary Biopsy Forceps (K121186).

7. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Radial Jaw™ 4 Pulmonary Biopsy Forceps is substantially equivalent to the currently cleared Radial Jaw™ 4 Pulmonary Biopsy Forceps (K121186).