December 30, 2022

Boston Scientific Corporation
Kyra Mcnamara
Regulatory Affairs Specialist II
100 Boston Scientific Way
Marlborough, MA 01752

Re: K223616
Trade/Device Name: Acquire™ S Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODG, FCG
Dated: December 2, 2022
Received: December 5, 2022

Dear Kyra Mcnamara:

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/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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K223616

Device Name
Acquire S endoscopic ultrasound fine needle biopsy (fnb) device

Indications for Use *(Describe)*
The Acquire S Fine Needle Biopsy Device is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope.

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.

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510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Primary Contact: Kyra McNamara
Regulatory Affairs Specialist II
Telephone: (508)-382-0375 Date
Prepared: December 2, 2022

2. Proposed Device:

Trade Name:	Acquire™ S Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device
Classification Name:	Endoscopic ultrasound system, gastroenterology-urology
Regulation Number:	21 CFR 876.1500 & 876.1075
Product Code:	ODG and FCG
Regulatory Class:	Class II

3. Predicate Device:

Trade Name:	Acquire ™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device
Manufacturer:	Boston Scientific
510(k) Number:	K160845
Classification Name:	Endoscopic ultrasound system, gastroenterology-urology
Regulation Number:	21 CFR 876.1500 & 876.1075
Product Code:	ODG and FCG
Regulatory Class:	Class II

4. Device Description:

Device Name: Acquire™ S Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device

The Acquire™ S device is comprised of the following:

- One (1) Acquire S™ needle
- One (1) Vacuum Syringe
- One (1) One-Way Stopcock

The Acquire™ S Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device is an endoscopic ultrasound biopsy needle that can be coupled to the biopsy channel of a Curvilinear Array (CLA) Echoendoscope with a standard luer connection and delivered into the digestive tract. The device sheath length can be adjusted to accommodate different model echoendoscopes. The needle is used to acquire samples from lesions within and adjacent to the digestive system's major lumens that can be identified and targeted using the echoendoscope. Both the sheath and needle length can be adjusted based on distance to the target lesion. The sheath and needle length adjustments are set and locked by the physician by using the locking knob mechanisms on the handle of the device. A sample is obtained by penetrating the lesion with the needle while applying suction and manipulating the needle in a back and forth motion to acquire a sample. The sample can be prepared per normal institutional protocol. The Acquire™ Needle has echogenic (visible under ultrasound) features at the distal end to facilitate real time visualization of the device under ultrasound.

Syringe and stopcock are accessories to provide and control the vacuum suction to aspirate the sample.

5. Intended use/ Indications for Use:

The Acquire™ S Fine Needle Biopsy Device is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope.

6. Technological Characteristics:

The proposed Acquire™ S device is a 139cm long needle used to acquire samples in the digestive tract by coupling it with an ultrasound curvilinear endoscope. The proposed Acquire™ S device is identical to the predicate Acquire™ device, with the exception of the stylet tip geometry. The proposed Acquire™ S device will have a taper point stylet, compared to the currently cleared Acquire™, which has a ball point stylet tip. The proposed Acquire™ S device shares the same technical characteristics as its predicate, the currently cleared Acquire ™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device (K160845).

7. Performance Data:

Non-clinical performance bench testing, simulated use testing, biocompatibility per the requirements of ISO 10993, and sterilization validation per the requirements of ISO 11135 were completed to evaluate the design of the Acquire™ S device for the change in stylet tip geometry.

Bench Testing included:

- Device Durability
- Stylet Removal Force
- Needle Extension Length
- Adjustable Catheter Length
- Stylet Cap Tensile

All testing was passing and demonstrates the device's ability to fulfill non-clinical performance bench testing, biocompatibility, and sterilization requirements.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Acquire™ S Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device is substantially equivalent to the currently cleared Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device (K160845).