March 2, 2023

Boston Scientific Corporation
Inderdeep Tiwana
Principal, Regulatory Affairs
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K221340
Trade/Device Name: iNod Ultrasound Guided Biopsy Needle (UPN: M00502060),
iNod Ultrasound Guidance Console (UPN: M00503210)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ, ITX, IYO, ODG
Dated: February 8, 2023
Received: February 9, 2023

Dear Inderdeep Tiwana:

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,

Ethan L. Nyberg -S

for James Lee, Ph.D
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*
K221430

Device Name
iNod Ultrasound Guidance Console

Indications for Use *(Describe)*

The iNod Ultrasound Guidance Console is intended to be used with iNod Ultrasound Guided Biopsy Needle, to observe and to store real-time ultrasound images of endobronchial lesions, peripheral lung nodules, or lung masses located in airways and tracheobronchial tree.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K221430

Device Name
iNod Ultrasound Guided Biopsy Needle

Indications for Use *(Describe)*

The iNod Ultrasound Guided Biopsy Needle is intended for use through a flexible bronchoscope for intraluminal sonographic imaging in the tracheobronchial tree and retrieval of specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses.

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)

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510(k) Summary for iNod Ultrasound Guidance System

1. Submitter

Boston Scientific Corporation
Endoscopy Division
100 Boston Scientific Way
Marlborough, MA 01752

Contact:

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Date Prepared: May 06, 2022

2. Device

Trade Name:	iNod Ultrasound Guided Biopsy Needle
Common Name:	Diagnostic Ultrasound Transducer Bronchoscope (flexible or rigid) and accessories
Product Code:	ITX and EOQ
Device Class:	Class II
Device Panel	Ear, Nose & Throat
Classification Regulation:	21 CFR.874.4680 Bronchoscope (flexible or rigid) and accessories
Trade Name:	iNod Ultrasound Guidance Console
Common Name:	IYO: System, imaging, pulsed echo, ultrasonic ITX: Diagnostic Ultrasound Transducer ODG: Endoscopic ultrasound system, gastroenterology-urology
Product Code:	IYO, ITX and ODG
Device Class:	Class II
Device Panel	Radiology and Gastroenterology and Urology
Classification Regulation:	21 CFR.892.1560 System, imaging, pulsed echo, ultrasonic

3. Predicate Devices

Proposed Device	**Component**	**Predicate Devices**
iNod Ultrasound Guidance System	iNod Ultrasound Guided Biopsy Needle	Probe: • Olympus Ultrasound Probe (K982323) Needle: • Arcpoint Pulmonary Needle (K163537)
	iNod Ultrasound Guidance Console	• EVIS EUS Endoscopic Ultrasound Center (K121564) • Avvigo Ultrasound System II (K212490)
	iNod Motor Drive Unit	• MDU5 Plus – 510K cleared with Avvigo Ultrasound System II (K212490)

4. Device Description

The proposed iNod Ultrasound Guidance System (iNod System), comprises: the sterile, single use iNod Ultrasound Guided Biopsy Needle (also referred to as iNod Single Use Device (SUD), iNod Ultrasound Guidance Console (iNod Console) and the iNod Motor Drive Unit (iNod MDU). The proposed iNod Ultrasound Guidance System is intended to perform pulmonary needle biopsy under real-time visualization using Radial Endobronchial Ultrasound (R-EBUS).

The iNod single-use-device (iNod SUD) is a single use, sterile device that has combined functionality of a radial ultrasound probe and a biopsy needle. The iNod SUD allows real-time visualization of pulmonary lesions with radial ultrasound, while simultaneously allowing biopsy of the pulmonary lesions. The three main parts of iNod SUD are a handle, a radial ultrasound transducer, and biopsy needle. The biopsy needle is actuated at an angle that allows biopsy of eccentric and concentric nodules. A stainless-steel needle indicator strip is housed in the imaging window at distal tip, which provides an ultrasound signature, indicating the orientation of the needle to the user in the ultrasound image. The biopsy needle will exit the iNod SUD distal tip at 180 degrees relative to the needle indicator position visible in the ultrasound image. Once the needle is positioned to biopsy a nodule, the needle is unlocked by user to the exit ramp at 11º angle. Finally, when a sample is collected, the Nitinol stylet can be passed down the needle lumen to expel the sample.

The iNod Console is an electronic device that consists of:

- The iNod MDU, which rotates the ultrasound transducer in the iNod SUD to generate 360° images as well as provides patient isolation from the rest of the Console components.
- A software-based touchscreen tablet with battery, which can be mounted to a mobile pole via the pole docking station.
- A software-based Acquisition PC that interprets the received ultrasound signals from the iNod SUD and generates the image that is displayed on the tablet.
- Functionality that displays ultrasonic image received from iNod SUD through iNod MDU and Acquisition PC on the iNod tablet and
- Ability to save and export procedure images and recordings.

The iNod MDU provides rotation of the iNod SUD's ultrasound transducer, required for generating a 360º ultrasound image. An electromechanical connector interface at the proximal end of the iNod SUD makes the connection to the MDU. The MDU-catheter interface consists of an integrated mechanical drive hub and electrical connection. The iNod Console interfaces with the iNod SUD through the iNod Motor Drive Unit (iNod MDU), which provides the electro-mechanics for the rotating parts of the imaging catheter, and the interface between the iNod SUD and the iNod console. The iNod MDU is nearly identical in design to its predicate MDU5 Plus, which is currently used with Avvigo Guidance System II (K212490).

5. Indications for Use

iNod Ultrasound Guided Biopsy Needle:
The iNod Ultrasound Guided Biopsy Needle is intended for use through a flexible bronchoscope for intraluminal sonographic imaging in the tracheobronchial tree and retrieval of specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses. .

iNod Ultrasound Guidance Console:
The iNod Ultrasound Guidance Console is intended to be used with iNod Ultrasound Guided Biopsy Needle, to observe and to store real-time ultrasound images of endobronchial lesions, peripheral lung nodules, or lung masses located in airways and tracheobronchial tree.

6. Technological Characteristics

The iNod Ultrasound Guided Biopsy Needle merges two devices: an ultrasound probe, and a lung biopsy needle, into one device. The vast majority of design characteristics are identical to the predicate devices, however, there are a few key technological differences between iNod SUD and its predicates. Performance testing has been executed to evaluate all design characteristics, as well as those in which there were differences in technological characteristics as compared to the predicates. The results of the bench-top testing were passing and demonstrates the proposed iNod SUD performs substantially equivalent to the predicate devices.

The iNod Ultrasound Guidance Console and its elements including the iNod MDU are nearly identical in design and physical attributes to its predicate AVVIGO Guidance System II (K212490). The main difference is the brand name, intended use as the AVVIGO Guidance System II is intended for use with catheters having cardiovascular indications for use, and removal of cardiovascular feature (pull-back feature) from the iNod MDU. All components and accessories of the proposed iNod Console are identical to the AVVIGO Guidance System II (K212490). In addition, the indications of use of the proposed iNod Console are identical to those of the primary predicate device, EVIS EUS Endoscopic Ultrasound (K203128) and there are no significant design differences between iNod Console and EVIS EUS Endoscopic Ultrasound (K203128).

7. Substantial Equivalence

The iNod Ultrasound Guided Biopsy Needle, iNod Console and iNod MDU devices are substantially equivalent to the following predicate devices.

Table 5-1 – Predicate Devices and 510(k) numbers

Proposed Device	Component	Predicate Devices
iNod Ultrasound Guidance System	iNod Ultrasound Guided Biopsy Needle	Probe: • Olympus Ultrasound Probe (K982323) Needle: • Arcpoint Pulmonary Needle (K163537)
	iNod Console	• EVIS EUS Endoscopic Ultrasound Center (K121564) • Avvigo Ultrasound System II (K212490)
	iNod MDU	• MDU5 Plus – 510K cleared with Avvigo Ultrasound System II (K212490)

8. Performance Data

Non-clinical (bench) testing was successfully performed on the proposed iNod Ultrasound Guided Biopsy Needle, iNod Ultrasound Guidance Console and the iNod System altogether. Performance testing (bench) that represents device's clinical use was successfully completed. In addition, all necessary software tests were performed for the iNod Software. The following bench testing was conducted to evaluate the changes on the proposed device. All Performance testing (bench) was successfully completed. The results of performance (bench) testing demonstrate that the proposed iNod Ultrasound Guided Biopsy Needle, iNod Ultrasound Guidance Console and iNod Motor Drive Unit (MDU) are considered substantially equivalent to the predicate devices.

Table 5-2 Bench/ Performance Testing Summary

Component	Product Specification	Results (Pass/Fail)
iNod SUD	Device Passability	Pass
iNod SUD	Device Rotation	Pass
iNod SUD	Needle Actuation Force	Pass
iNod SUD	Needle Extension Length	Pass
iNod SUD	Needle Angle	Pass
iNod SUD	Needle Outer Diameter	Pass
iNod SUD	Needle Inner Diameter	Pass
iNod SUD	Needle Sharpness	Pass
iNod SUD	Needle Aspiration	Pass
iNod SUD	Stylet Removal Force	Pass
iNod SUD	Stylet Kink Resistance	Pass
iNod SUD	Catheter Working Length	Pass

Component	Product Specification	Results (Pass/Fail)
iNod SUD	Handle to Catheter Tensile	Pass
iNod SUD	Drive Cable to Handle Tensile	Pass
iNod SUD	Drive Cable to MDU Connector Tensile	Pass
iNod SUD	Device Reliability	Pass
iNod SUD	Pulse Echo Sensitivity	Pass
iNod SUD	Pulse Echo Bandwidth	Pass
iNod SUD	Pulse Echo Center Frequency	Pass
iNod SUD	Pulse Echo Pulse Length	Pass
iNod SUD	Acoustic Output	Pass
iNod SUD	NURD (Non-Uniform Rotation Distortion)	Pass
iNod SUD	Needle Lock Override Force	Pass
iNod SUD	ISO 80369 Small-bore connectors for liquid and gases in healthcare applications	Pass
iNod SUD	ISO 9626 Stainless Steel Needle Tubing for Manufacture of Medical Devices – Requirements and test methods	Pass
iNod SUD	Catheter Drive Cable Length	Pass
iNod SUD	Device Bronchoscopic Visibility	Pass
iNod SUD	Device Radiopacity	Pass
iNod SUD	Needle Indicator	Pass
iNod SUD	Needle Lock Engage/Disengage Force	Pass
iNod SUD	Handle Grip Area	Pass
iNod SUD	Actuation Mechanism Location	Pass
iNod SUD	Needle Locking Mechanism Location	Pass
iNod SUD	Handle Rotation	Pass
iNod SUD	Product can be held with scope	Pass
iNod SUD	Catheter Outer Diameter	Pass
iNod SUD	Imaging System Compatibility	Pass
iNod SUD	Motor Drive Compatibility - Torque	Pass
iNod SUD	Motor Drive Compatibility – Load	Pass
iNod SUD	Needle Exit Location	Pass
iNod Console	Archive Case Studies	Pass
iNod Console	Create Case Study	Pass
iNod Console	Annotate	Pass
iNod Console	Patient Display	Pass
iNod Console	Add Snapshots	Pass
iNod Console	Select and Review Case Studies	Pass
iNod Console	Export Event Logs	Pass
iNod Console	Export Recordings and Screenshots	Pass
iNod Console	Import/Export Case studies	Pass
iNod Console	Patient List Query	Pass
iNod Console	Select Patient	Pass
iNod Console	Mobile Configuration	Pass
iNod Console	Record Management	Pass
iNod Console	Default Modality	Pass
iNod Console	Power-On Self Test Status	Pass
iNod Console	Operating System	Pass
iNod Console	Power Up Duration	Pass
iNod Console	DICOM Archiving Performance	Pass
iNod Console	Expected Service Life	Pass
iNod Console	PII and ePHI data encryption	Pass

Component	Product Specification	Results (Pass/Fail)
iNod Console	System Access to health delivery organization network	Pass
iNod Console	User Control	Pass
iNod Console	System Displays	Pass
iNod Console	Image Artifact Removal	Pass
iNod Console	Start Recording	Pass
iNod Console	Stop Recording	Pass
iNod Console	Linear Measurement on Ultrasound Frame	Pass
iNod Console	Imaging Depth	Pass
iNod Console	Distance Accuracy on Ultrasound Frame	Pass
iNod Console	Image Frame Rate: Ultrasound catheters	Pass
iNod Console	Gap detection	Pass
iNod Console	Catheter compatibility and Bandwidth	Pass
iNod Console	SUD Retention Force	Pass
iNod MDU	Receive Path Spectral Response	Pass
iNod MDU	Bi-Polar Tx – P-P Output Voltage Amplitude	Pass
iNod MDU	Pulse Uniformity – Bi-Polar Pulses	Pass
iNod MDU	Bi-Polar Output Bandwidth	Pass
iNod MDU	Receive Path Common Mode Gain	Pass
iNod MDU	RF Receive Path Noise Figure	Pass
iNod MDU	Receive Path Spurious Noise	Pass
iNod MDU	Pull Force and Side Force	Pass
iNod MDU	Rotational Speed	Pass

iNod Ultrasound Guided Biopsy Needle is sterilized using E-beam sterilization method and E-Beam Radiation cycle is validated per Method VDmax27.5 to a sterility assurance level of 10^{-6} in accordance with EN ISO 11137-1: 2006, EN ISO 11137-2: 2013, and ISO TS13004:2014. Validation included dose mapping, bioburden assessment, and dose audit / dose verification testing to validate an SAL of 10^{-6} in routine sterilization processing. All relevant aspects of the applicable standards were met. In addition, the iNod Ultrasound Guided Biopsy Needle is undergoing routine bacterial endotoxins test (BET), also known as the Limulus amebocyte lysate (LAL) test, in accordance with standard AAMI/ANSI ST72: Bacterial endotoxin – test methods, routine monitoring and alternatives to batch resting (Sterility).

Biocompatibility of the proposed iNod Ultrasound Guided Biopsy Needle was evaluated in accordance with ISO 10993-1. Based on the biocompatibility classification of the device the following biocompatibility tests were conducted: Cytotoxicity, Sensitization, Irritation, Toxicity, and Pyrogen Testing.

Lastly, iNod Ultrasound Guidance System was evaluated for electrical safety under electoral safety standards ISO 60601-1, ISO 60601-1-2, ISO 60601-1-6, 60601-2-18 and ISO 60601-2-37. All tests met the predefined requirements and further support the safety of the proposed devices.

9. Conclusion

Boston Scientific has demonstrated that the proposed iNod Ultrasound Guidance System is substantially equivalent to the currently marketed predicate devices.