March 8, 2019

Boston Scientific Corporation
Elena Nieves
Fellow, Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K183085
Trade/Device Name: CoreDx™ Pulmonary Mini-Forceps
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: February 5, 2019
Received: February 6, 2018

Dear Elena Nieves:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183085

Device Name
CoreDx Pulmonary Mini-Forceps

Indications for Use *(Describe)*
The CoreDx Pulmonary Mini-Forceps are specifically designed to collect tissue endoscopically for histologic examination. These forceps can be used with endobronchial ultrasound endoscopes for ultrasound guided mini-forceps biopsy (MFB) of submucosal and extramural lesions of the tracheobronchial tree. These forceps should not be used for any purpose other than their intended use.

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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510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Elena Nieves
Fellow Regulatory Affairs Specialist
Tel: 508-683-4347
Fax: 508-683-5939
Date Prepared: November 5, 2018

2. Proposed Device:

Trade Name:	CoreDx™ Pulmonary Mini-Forceps
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	874.4680
Product Code:	EOQ
Classification:	Class II

3. Predicate Device:

Trade Name:	Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	874.4680
Product Code:	EOQ
Classification:	Class II
510(k) Clearance Number:	K163248

4. Reference Device:

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

5. Device Description:

The CoreDx Pulmonary Mini-Forceps is a sterile, single use device comprised of jaws at the distal tip, attached to a flexible coil with a spool and a thumb ring handle attached at the proximal end of the device. The two radial jaws are attached to an actuation mechanism and can be opened and closed by sliding the spool handle. The jaws are designed to tear and retain tissues within the jaws. Once the CoreDx Pulmonary Mini-Forceps is positioned at the target area, the radial jaws are opened and a sample of tissue is collected for histological examination. The CoreDx Pulmonary Mini-Forceps are designed to be compatible with scopes that have a working channel with a minimum inner diameter (ID) of 1.2 mm. The CoreDx™ Pulmonary Mini-Forceps is designed for

use in the pulmonary system. The proposed device can also be used following an EBUS Transbronchial Needle Aspiration (EBUS-TBNA) procedure to pass through the airway wall and access a lymph node via an EBUS scope.

6. Indications for Use:
The CoreDx Pulmonary Mini-Forceps are specifically designed to collect tissue endoscopically for histologic examination. These forceps can be used with endobronchial ultrasound endoscopes for ultrasound guided mini-forceps biopsy (MFB) of submucosal and extramural lesions of the tracheobronchial tree. These forceps should not be used for any purpose other than their intended use.

7. Technological Characteristics:
The proposed CoreDx Pulmonary Mini-Forceps has different technological characteristics compared to the primary predicate Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle (K163248). However, both the proposed and primary predicate device can pass through the scope to the target position. In addition, the materials of the distal section of the proposed and primary predicate are echogenic for visibility under ultrasound.

The proposed CoreDx Pulmonary Mini-Forceps has the same indications for use as the primary predicate Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle (K163248) and reference device Radial Jaw™ 4 Pulmonary Biopsy Forceps (K121186). However, the proposed device's working length is 130cm which is longer than the predicate devices in order to access the lung periphery. The proposed CoreDx will also be compatible with currently available digital and ultrasound bronchoscopes. In addition, the proposed device is designed to be compatible with scopes that have a working channel with a minimum inner diameter (ID) of 1.2 mm. Therefore, the dimensions of the proposed device better suit the airway anatomy to ensure market needs are adequality addressed, as the proposed CoreDx Pulmonary Mini-Forceps can be used in the lung periphery.

The proposed CoreDx Pulmonary Mini-Forceps and the primary predicate Expect Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle are intended to be used to obtain tissue samples from the lymph node (one sample acquired and removed in each pass) through the EBUS-TBNA needle puncture hole within and adjacent to the major lumens of the airway that can be identified and targeted using the ultrasound bronchoscope. The proposed CoreDx will follow the same track through the scope and puncture hole as that of the EBUS-TBNA needle. Both the CoreDx and the Expect Pulmonary can reach lesions that require extension beyond the bronchial wall. Extension beyond the bronchial wall may be required in order to access lymph nodes or anatomies such as the lung that a physician is interested in obtaining a biopsy sample. Accessing the lung may be intentional and is considered a standard EBUS-TBNA procedure.

When the proposed CoreDx™ Pulmonary Mini-Forceps is compared to the primary predicate Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle, both devices have technological characteristics which include catheter based

technology with actuating handles that slightly differ as the proposed includes a handle with a thumb ring while the primary predicate includes a handle with a base. Both the proposed and primary device serve the same function and are intended to be used to obtain tissue samples from the lymph node (one sample acquired and removed in each pass) through the EBUS-TBNA needle puncture hole within and adjacent to the major lumens of the airway that can be identified and targeted using the ultrasound bronchoscope. The difference is that the proposed CoreDx has jaws to obtain tissue samples while the primary predict Expect has a needle to obtain tissue samples, therefore, both devices serve the same function of taking tissue samples.

When the proposed CoreDx is compared to the reference device Radial Jaw™ 4 Pulmonary Biopsy Forceps, the technological characteristics are similar as both devices have a catheter base and the same technology of actuating the handle, opening and closing the jaw. The only technological difference is the length of the proposed device which is longer and was evaluated through bench testing (i.e. Working Length).

8. Performance Data:
The proposed device meets the requirements of ISO 10993 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing". Testing that was performed include Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, and USP Rabbit Pyrogen Testing; ISO 11135-1 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices", and ISO 10993-7 "Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals".

The following bench tests were performed on the CoreDx Pulmonary Mini-Forceps: Passability; Pushability; Working Length; Device Reliability; Forceps Operation; Forceps Integrity; and Smooth Edges.

In addition, the proposed device was evaluated for visibility under ultrasound after a standard EBUS-TBNA procedure in a swine lung model which was confirmed through user feedback assessment.

The non-clinical testing that was performed and submitted demonstrated that the proposed CoreDx Pulmonary Mini-Forceps is substantially equivalent to the primary predicate and reference devices as the performance of the proposed device meets the requirements of its pre-defined acceptance criteria and intended use.

9. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed CoreDx Pulmonary Mini-Forceps is substantially equivalent to the currently cleared Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle (K163248) as the performance of the proposed device meets the requirements of its pre-defined acceptance criteria and intended use.