DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 24,2015

Cyndy Adams
Senior Regulatory Affairs Manager
Spiration, Inc.
6675 185th Avenue Ne
Redmond, WA 98052

Re: K142909
Trade/Device Name: Flexible 19G EBUS Needle
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: EOQ
Dated: March 26, 2015
Received: March 27, 2015

Dear Ms. Adams:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Division 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142909

Device Name
Flexible 19G EBUS Needle

Indications for Use *(Describe)*
The Flexible 19G EBUS Needle has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree. Do not use this device for any purpose other than its 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.

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."

510(k) Summary

Submitter Information

Date of 510(k) Summary Preparation:	April 24, 2015
Name and Address of Manufacturer:	Spiration, Inc. 6675 185th Avenue Ne Redmond, WA 98052
Contact Person:	Cyndy Adams Senior Regulatory Affairs Manager Phone: (425) 497.1700 Fax: (425) 497.8802

Subject Device

Device Trade Name:	Flexible 19G EBUS Needle
Common Name:	Aspiration Needle
Classification:	
Regulation:	Bronchoscope (flexible or rigid) and accessories 21 CFR 874.4680
Product Code:	EOQ
Review Panel:	ENT

Predicate Device

Trade Name:	Single Use Aspiration Needle
510(k) Number:	K050503, cleared 05/12/05
Manufacturer:	Olympus Medical Systems Corporation

Device Description

The Flexible 19G EBUS Needle is intended for use with compatible ultrasound endoscopes for Transbronchial Needle Aspiration (TBNA) of submucosal and extramural lesions of the tracheobronchial tree. The device is supplied sterile and intended for single patient use.

The device consists of a handle, sheath, needle, and stylet. The sheath and needle are attached to the handle, and the removable stylet is located within the needle.

To perform biopsies, the flexible catheter portion is first inserted into a bronchoscope's working channel (2.2mm) then pushed forward until fully inserted. The handle is then affixed to the channel port of the endoscope using an adapter biopsy valve. The handle facilitates advancement of the needle during puncture of the targeted biopsy site. The sample is obtained by penetrating the lesion with the needle while applying suction at the proximal of the handle. The device is available with a needle size of 19 gauge (19G).

Indications for Use

The Flexible 19G EBUS Needle has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree. Do not use this device for any purpose other than its intended use.

Comparison to Predicate

The Flexible 19G EBUS Needle (19G Needle) is substantially equivalent to the currently marketed predicate, the Olympus Single Use Aspiration Needle cleared under K050503. The 19G Needle has the same technological characteristics as the predicate, that is, they operate in the same manner to obtain a tissue biopsy using an ultrasound endoscope. The intended use of the 19G Needle is a subset of the predicate intended use.

The 19G Needle has a larger, more flexible distal tip relative to the predicate device. A comparison of the 19G Needle and the Olympus Aspiration Needle is provided in the following table.

Comparison of Key Characteristics

	Predicate Device (K050503)	**Subject Device**
Device Characteristics	**Olympus 22G & 21G Needles**	**Flexible 19G EBUS Needle**
Indications for Use	This instrument has been designed to be used with ultrasonic endoscopes for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract. Do not use this instrument for any purpose other than its intended use.	The Flexible 19G EBUS Needle has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree. Do not use this device for any purpose other than its intended use.
Use Conditions	Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope	Identical
Mechanics of Action	Manual	Identical
Mode of Action	Single/multiple puncture and aspirate	Identical
General Design	Handle, Sheath, Needle, Stylet	Identical
Materials	Biocompatible per 10993-1	
	PTFE Stainless Steel Nitinol	PTFE Stainless Steel Nitinol PEBAX HDPE
Product Specifications and Properties	Engineering bench testing confirms that the Olympus 19G Needle meets its product specifications, which are equivalent to those of the predicate Olympus Aspiration Needles, including the 21G.	
Sterilization	EO	Identical
Single Use Only	Yes	Identical
Working Outside Diameter (mm)	1.9	Identical
Catheter Length (cm)	70	Identical

	Predicate Device (K050503)	Subject Device
Device Characteristics	**Olympus 22G & 21G Needles**	**Flexible 19G EBUS Needle**
Needle gauge size	22G & 21G	19G
Typical Needle Length (mm)	20	Identical
Max Needle Length (mm)	40	Identical

Performance Data

Device performance of the Flexible 19G EBUS Needle was verified through in vitro (bench) and *ex vivo* testing. Testing was designed to mimic stresses encountered in a clinical setting; acceptance criteria (specifications) were either identical to those of the predicate or established to verify design differences in the 19G Needle relative to the predicate. All testing met the pre-determined acceptance criteria as outlined in the test protocols.

Testing to Specifications Identical to the those of the Predicate

Insertion and Withdrawal Force	Pass
Stylet Insertion and Withdrawal Force	Pass
Activation Force	Pass
Plastic Deformation Angle	Pass
Durability	Pass
Handle Durability	Pass

Testing to Specifications Developed for the 19G Needle

(These were deemed important parameters to test on the 19G Needle. Where relevant, the predicate was also tested.)

Bronchoscope Angulation	Pass
Penetration Force [1]	Pass
Transmission Force	Pass
Vacuum Leak Test	Pass
Sheath to Handle Joint Strength	Pass
Echogenicity [2]	Pass
Biopsy Sample Size[1, 2]	Pass
Simulated use – *ex vivo* (bovine lung) bench testing	Pass

[1] For direct comparison to a commercially available device of the same size, testing was also conducted on the Boston Scientific 19G Scientific eXcelon Transbronchial Aspiration Needle.
[2] Testing also conducted on the predicate 21G Olympus Aspiration Needle.

Additional Testing of the 19G Needle to Support Substantial Equivalence

Sterilization Validation	Pass
Packaging and Shelf Life	Pass
Biocompatibility	
Cytotoxicity (MEM Elution)	Pass
Sensitization (Maximization)	Pass

Irritation (Intracutaneous Reactivity)	Pass
Hemocompatibility (Extract and Direct Contact Hemolysis)	Pass
Systemic Toxicity (Systemic Injection and Material Mediated Pyrogen)	Pass

The results from this testing demonstrate that the performance and technological characteristics of the Flexible 19G EBUS Needle meet defined design requirements and that the device performs equivalently to the predicate aspiration needle devices for its intended use.

Conclusion (Statement of Equivalence)

The data and information presented within this 510(k) Premarket Notification (including in vitro bench and *ex vivo* testing) support a determination of substantial equivalence, and therefore market clearance of the Flexible 19G EBUS Needle.