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

February 19, 2016

Spiration, Inc.
Ms. Cyndy J. Adams
Senior Manager Regulatory
6675 185th Ave NE
Redmond, Washington, 98052

Re: K152922
Trade/Device Name: ViziShot FLEX
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories.
Regulatory Class: II
Product Code: KTI
Dated: January 19, 2016
Received: January 21, 2016

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
ViziShot FLEX

Indications for Use *(Describe)*
The ViziShot FLEX 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 of the 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.

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1 510(k) Summary

Submitter Information

Date of 510(k) Summary Preparation:	February 19, 2016
Name and Address of Manufacturer:	Spiration, Inc. 6675 185th Avenue Ne Redmond, WA 98052
Contact Person:	Cyndy Adams Senior Regulatory Affairs Manager Phone: (425) 636.5450 Fax: (425) 497.8802

Subject Device

Device Trade Name:	ViziShot FLEX
Common Name:	Aspiration Needle
Classification:	Bronchoscope (flexible or rigid) and accessories
Regulation:	21 CFR 874.4680
Product Code:	KTI
Review Panel:	ENT

Predicate Device

Trade Name:	Flexible 19G EBUS Needle
510(k) Number:	K142909, cleared 4/24/2015
Manufacturer:	Spiration, Inc.

Device Description

The ViziShot FLEX 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. Note that although the device has a component called a needle, the device is often referred to as a needle as well.

Prior to a procedure, the flexible catheter portion is inserted into a bronchoscope's working channel (2.2mm) and advanced forward until fully inserted. The handle is then affixed to the channel port of the endoscope via a lever mechanism that locks onto the Adapter Biopsy Valve. The needle is advanced through the bronchoscope to the sampling site while visualizing both the target and the needle in real time with ultrasound. 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 end of the handle. After completing the sampling, the vacuum from the syringe is released to atmosphere, the handle unlocked from the bronchoscope, and the catheter and needle pulled out from the working channel. The removed tissue can then be prepared for cytopathological or microbiological examination and testing.

The ViziShot FLEX is available in one model only (NA-U402SX-4019), with a needle size of 19 gauge (19G). The two required accessories, the Olympus Adapter Biopsy Valve and the Merit Syringe with Stopcock, are packaged with the ViziShot FLEX.

Indications for Use

The ViziShot FLEX 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.

Technological Characteristics

The technological characteristics of the ViziShot FLEX are the same as those of the predicate Flexible 19G EBUS Needle. That is they have substantially the same design, material, and energy source. They are both designed to obtain a sample from lung tissue or lymph node tissue under ultrasound visualization. Both devices have the following technological characteristics:

- Needle length adjustable and lockable
- Sheath length adjustable and lockable
- Secure attachment to scope with controlled device orientation
- Manual needle movement through bronchoscope to target site
- Flexible needle
- Stylet resistant to kinking
- Echogenic needle tip visible with ultrasound
- Sharp needle tip
- Aspiration capability

Comparison to Predicate

The ViziShot FLEX has the same technological characteristics as the predicate Flexible 19G EBUS Needle cleared under K142909. The subject and predicate device operate in the same manner to obtain a tissue biopsy using an ultrasound endoscope. The indications for use of the ViziShot FLEX is the same as that of the predicate.

The ViziShot FLEX has a slightly less flexible distal tip and a slightly larger stylet relative to the predicate device and the required accessories are packaged with the device. A detailed comparison of the ViziShot FLEX Needle and the Flexible 19G EBUS Needle is provided in the following table.

Comparison of Key Characteristics

	Predicate Device (K142909)	**Modified Device**
Device Name→ **Device Characteristics ↓**	**Flexible 19G EBUS Needle**	**ViziShot FLEX**
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.	The ViziShot FLEX 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
Patient Contacting Material	Stainless Steel, PTFE, PEBAX, Nitinol	Identical
Biocompatible	Yes	Identical
Product Specifications and Properties	Engineering bench testing confirms that the modified 19G Needle meets its product specifications, which are equivalent to those of the predicate 19G Needle	
Sterilization	EO	Identical
Single Use Only	Yes	Identical

	Predicate Device (K142909)	Modified Device
Device Name→ **Device Characteristics ↓**	**Flexible 19G EBUS Needle**	**ViziShot FLEX**
Working OD (mm)	1.9	2.08
Catheter Length (cm)	70	Identical
Needle Gauge	19G	Identical
Typical Needle Length (mm)	20	Identical
Max Needle Length (mm)	40	Identical
Stylet OD (in)	0.0177	0.0205
Stylet Surface Finish	Not polished	Polished
Accessories	User acquires	Identical accessories provided with device

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

Device performance of the ViziShot FLEX was verified through in vitro (bench) and *ex vivo* testing. Testing was designed to mimic stresses encountered in a clinical setting. All testing met the pre-determined acceptance criteria as outlined in the test protocols.

Sheath and Needle Insertion and Withdrawal Force
Stylet Insertion and Withdrawal Force
Bronchoscope Angulation
Activation Force
Plastic Deformation Angle
Penetration Force
Transmission Force
Durability
Vacuum Leak Test
Bronchoscope Adapter Sliding Force
Handle Durability
Sheath to Handle Joint Strength
Echogenicity
Simulated use – *ex vivo* (bovine lung) bench testing

In simulated use testing, the following aspects of device use were evaluated:

- Able to connect to endoscope using supplied adapter biopsy valve
- Remains functional after exposure to saline, water, and water-based lubricants
- Single operator is able to collect a tissue sample
- Able to aspirate and expulse tissue

Sterilization Validation

The ViziShot FLEX is EO sterilized with a cycle that has been validated in accordance with EN ISO 11135:2014. This cycle is validated to assure the ViziShot FLEX achieves a 10^{-6} SAL. EO residual and Endotoxin test results also met acceptance criteria with results below the limits dictated by ISO 10993-7 for residuals and below the endotoxin limits of 20 EU/device.

Biocompatibility

Spiration considered ISO 10993-1, the ODE Blue Book Memorandum #G95-1 (1995), Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," and the FDA draft guidance "Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing (4/23/13)" in determining the applicable tests and test methods for biocompatibility testing. As an external communicating device with a limited blood path indirect exposure (<24 hours), the ViziShot FLEX the following battery of tests is required:

- Cytotoxicity
- Sensitization
- Irritation
- Hemocompatibilty
- Systemic Toxicity

The full battery of tests was conducted on the patient contacting/fluid path portion of the predicate Flexible 19G EBUS Needle; all testing passed. Because the only material change in the ViziShot FLEX Needle, is a supplier change in a non-patient contacting, non-fluid path component, only cytotoxicity was conducted on the ViziShot FLEX; this testing passed.

The results from this testing demonstrate that the performance and technological characteristics of the ViziShot FLEX meet defined design requirements and that the device performs equivalently to the predicate Flexible 19G EBUS Needle.

Conclusion

The data and information presented within this 510(k) Premarket Notification support the substantial equivalence of the ViziShot FLEX to the cleared Flexible 19G EBUS Needle.