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 9, 2017

Spiration, Inc.
Aadarsh Viswanathan
Regulatory Specialist
6675 185th Ave NE
Redmond, Washington 98052

Re: K162611
Trade/Device Name: Periflex
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: January 10, 2017
Received: January 11, 2017

Dear Aadarsh Viswanathan:

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" (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 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,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162611

Device Name
PeriFLEX

Indications for Use *(Describe)*
This device is intended to be used through a compatible bronchoscope for the collection of tissue from the intrapulmonary regions. Do not use 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:	February 3, 2017
Name and Address of Manufacturer:	Spiration, Inc. 6675 185th Avenue NE Redmond, WA 98052
Contact Person:	Aadarsh S. Viswanathan Regulatory Affairs Specialist Phone: (425) 636.5535 Fax: (425) 497.8802

Subject Device

Device Trade Name:	PeriFLEX
Common Name:	Transbronchial Aspiration Needle
Classification:	II
Regulation:	Bronchoscope (flexible or rigid) and accessories 21 CFR 874.4680
Product Code:	EOQ
Review Panel:	ENTB

Predicate Device

Trade Name:	Wang MW-222 Transbronchial Aspiration Needle
510(k) Number:	K914181
Manufacturer:	Conmed, Inc.

Reference Device

Trade Name:	Olympus NA-1C Needle
510(k) Number:	K904667
Manufacturer:	Olympus Corporation

Device Description

The PeriFLEX Needle is intended to be used through a compatible bronchoscope for the collection of tissue from the intrapulmonary regions. The device is supplied sterile and intended for single patient use.

The main components of the device are a handle, a sheath, a needle, and a stylet. The sheath and needle (together termed the insertion portion) are attached to the handle. The removable stylet runs the full length of the device and fits inside the lumen of the handle and the needle.

The needle is housed within the sheath. These components, i.e., the insertion portion, are inserted into the working channel of the endoscope and advanced to the target site. The handle is connected to the insertion portion and has a needle slider component. The needle slider is controlled manually by the user to extend and retract the needle from the sheath at the target site. Once a sample is collected, the stylet may be used to assist with removing the sample from the needle.

The PeriFLEX Needle is available in one model only (PERIFLEX-21G), with a needle size of 21 gauge (21G). The PeriFLEX Needle can be used with the following accessories: vacuum syringe (to assist with sample collection), biopsy valve (to assist with creating a vacuum), and guide sheath (to extend the working length). However, these accessories are not included with the PeriFLEX Needle's packaging and must be obtained separately by the user.

Indications for Use

The PeriFLEX Needle is intended to be used through a compatible bronchoscope for the collection of tissue from the intrapulmonary regions. Do not use for any purpose other than its intended use.

Comparison to Predicate Device

The PeriFLEX Needle is *substantially equivalent* to the chosen predicate, the Conmed Wang MW-222 Needle cleared under K914181. The PeriFLEX Needle has similar technological characteristics as the predicate device; there are no differences that raise different questions of safety and effectiveness relative to the predicate devices. Both devices operate in the same manner to obtain a tissue biopsy using a bronchoscope.

The primary difference between the subject and predicate device lies in the flexibility of the needle; the PeriFLEX Needle has a more flexible tip than the predicate device. Other differences between the subject device and the predicate device include a smaller diameter to facilitate compatibility with newer bronchoscopes with smaller working channels and a longer needle for better accessibility to distal lesions.

A detailed comparison of the PeriFLEX Needle, the chosen predicate device, and the reference device is provided in the following table.

Comparison of Predicates and the PeriFLEX Needle

	PeriFLEX Needle **(K162611)** **(Subject Device)**	**Conmed Wang MW-222 Needle** **(K914181)** **(Predicate Device)**	**Olympus NA-1C Needle** **(K904667)** **(Reference Device)**
Intended Use Statement	This device is intended to be used through a compatible bronchoscope for the collection of tissue from the intrapulmonary regions. Do not use for any purpose other than its intended use	Used to puncture the trachobronchial wall and aspirate sufficient tissue and/or cell specimens to stage bronchogenic carcinoma.	These needles are intended for endoscopic submucosal and extra-bronchial aspiration of tissue and fluids. Do not use them for any purpose other than their intended function.
Anatomical Site	Lung	Lung	Lung
Use Conditions	Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope	Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope	Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope
Intended User	By or under the supervision of a physician	By or under the supervision of a physician	By or under the supervision of a physician
Mechanics of Action	Manual	Manual	Manual
Mode of Action	Single/multiple puncture and aspirate	Single/multiple puncture and aspirate	Single/multiple puncture and aspirate
General Design	Handle, Sheath, Needle, Stylet	Handle, Sheath, Needle, Stylet	Handle, Sheath, Needle, Stylet
Biocompatible	Yes	Yes	Yes
Patient Contacting & Fluid Path Materials	Stainless Steel, PEBAX, PTFE, Nitinol	Stainless Steel, Teflon (PTFE)	Information Not Available
Sterility	Sterile	Sterile	Sterile (the sheath must be sterilized before use by the user)
Sterilization Method	Ethylene Oxide	Information Not Available	Ethylene Oxide (30%)/CO_2 (70%)
Single Use Only	Single Use Only	Single-Use Only	Single Use Needle Section, Reusable Sheath
Working OD (mm)	1.5	1.9	1.8
Catheter Length (cm)	115	140	105
Catheter Cross Section	Single Lumen	Single and Double Lumen Available	Single Lumen

	PeriFLEX Needle (K162611) (Subject Device)	Conmed Wang MW-222 Needle (K914181) (Predicate Device)	Olympus NA-1C Needle (K904667) (Reference Device)
Needle Gauge (Size)	21G	22G	21G
Needle Tip Material	Stainless Steel	Stainless Steel	Stainless Steel
Needle Length (mm)	20	13	13
Needle Flexibility	Distal 20 cm flexible due to laser-cut.	Information Not Available	Not designed for greater flexibility
Stylet OD (in)	0.0185	Information Not Available	0.0115

Performance Data

Device performance of the PeriFLEX Needle 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
Handle Activation Force
Plastic Deformation Angle
Transmission Force
Handle Assembly Strength
Handle Durability
Durability
Vacuum Leak Test
Sheath to Handle Joint Strength
Biopsy Sample Size[1]
Simulated use – *ex vivo* (bovine lung) bench testing

[1] For direct comparison to a reference device, testing was also conducted on the Olympus NA-1C Needle

Additional Testing of the PeriFLEX Needle to Support Safety and Effectiveness

- Sterilization Validation
  - Product Adoption
  - Comparative Resistance
- Packaging and Shelf Life
- Biocompatibility
  - Cytotoxicity (MEM Elution)
  - Sensitization (Magnusson-Kligman Method)
  - Irritation (Intracutaneous Toxicity)
  - Hemocompatibility (Indirect and Direct Contact)
  - Toxicity
  - Pyrogenicity

The results from this testing demonstrate that the performance and technological characteristics of the PeriFLEX Needle meet defined design requirements and that the device performs equivalently to the predicate aspiration needles.

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 of the PeriFLEX Needle to the cleared Conmed Wang MW-222 Needle.