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

September 21, 2017

Olympus Surgical Technologies America
Ms. Mary Patella
Senior Specialist, Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts 01772-2104

Re: K171232
Trade/Device Name: PeriView FLEX
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: August 21, 2017
Received: August 22, 2017

Dear Ms. Patella:

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 (DICE) 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 (DICE) 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,

Tara A. Ryan -S
2017.09.21 05:52:34 -04'00'

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)*

Device Name
PeriView FLEX

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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
Gyrus ACMI ViziShot 2 FLEX

General Information

Manufacturer:	Olympus Surgical Technologies America Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104 Phone: 508-804-2600 Fax: 508-804-2624
Establishment Registration Number:	3003790304
Contact Person:	Mary Anne Patella Senior Specialist, Regulatory Affairs 508-804-2771 Maryanne.patella@olympus-osta.com
Date Prepared:	April 25, 2017

Device Description

Classification Name:	Bronchoscope (flexible or rigid) and accessories
CFR Citation Number:	21 CFR 874.4680
Product Code:	KTI
Classification:	Class II
Review Panel	Ear Nose & Throat
Trade Name:	PeriView FLEX
Generic/Common Name:	Aspiration Needle

Predicate Devices

Spiration, Inc. PeriFLEX	K162611

Product Description

The PeriView FLEX 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 is intended for single patient use.

The device consists of a handle, sheath, needle, and stylet. The sheath and needle (together termed the *insertion section*) are attached to the handle and needle slider respectively. The removable stylet runs the full length of the device and is located within the lumen of the needle. Note that although, the device has a component called a needle, the device is often referred to as a needle as well.

The distal end of the insertion portion (sheath and needle) of the PeriView FLEX needle is inserted into the working channel of the bronchoscope 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, an air filled syringe or the stylet can be used to expel the sample from the needle.

The PeriView FLEX is available in one model only (NA-403D-2021), with a needle size of 21gauge (21G). The PeriView FLEX Needle can be used with the following optional accessories: vacuum syringe, biopsy valve, and guide sheath. These optional accessories are not included with the PeriView FLEX Needle's packaging and must be obtained separately by the user.

Intended Use

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.

The Intended Use is identical to that of the predicate device.

Comparison of Technological Characteristics

The PeriView FLEX has the same basic technological characteristics as the predicate PeriFLEX cleared under K162611. The subject and predicate device operate in the same manner to obtain tissue using a bronchoscope. The indications for use of the PeriView FLEX are the same as that of the predicate.

The PeriView FLEX handle profile design has been changed from the predicate device to improve ergonomics; as well as to utilize Design for Manufacturing principles to make assembly more efficient. The resulting device functionality and interaction with the physician are equivalent to those of the predicate device PeriFLEX.

The bronchoscope angulation specification for the PeriView FLEX differs slightly from that of the predicate to accommodate bronchoscope to bronchoscope angulation variability. The proposed device has demonstrated the ability to reach the upper lobes of the lung; thereby affirming equivalence to the predicate device.

A detailed comparison of the PeriView FLEX and the PeriFLEX is provided in the following table.

Table 5.1 Comparison of Proposed and Predicate Device

	Predicate Device (K162611)	**Proposed Device**
Device Characteristic	**PeriFLEX**	**PeriView FLEX**
Indications for Use	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.	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.
Anatomical Site	Lung	Identical
Use Conditions	Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope	Identical
Intended User	By or under the supervision of a physician	Identical
Mechanics of Action	Manual	Identical
Mode of Action	Single/multiple puncture and aspirate	Identical
General design	Handle, Sheath, Needle, Stylet	Sheath, Needle & Stylet are identical. The handle design has been changed to improve ergonomics and to utilize Design for Manufacturing principles.
Patient Contacting Materials	Stainless Steel, PTFE, PEBAX, Nitinol	Identical
Biocompatible	Yes	Yes
Sterilization	Ethylene Oxide	Ethylene Oxide
Single Use Only	Yes	Identical
Maximum Working OD (mm)	1.5	Identical
Catheter Length (cm)	115	Identical
Needle Gauge	21G	Identical
Typical Needle Length (mm)	20	Identical
Stylet OD (in)	0.0185	Identical

Summary of Non-Clinical Testing

Biocompatibility:
Biocompatibility testing on all patient contacting surfaces has been performed in compliance to relevant requirements of ISO-10993. Biocompatibility testing included the following tests:

- ISO 10993-4: 2002 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
- ISO 10993-5: 2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of medical devices. Tests for irritation and sensitization
- ISO 10993-11:2006. Biological evaluation of medical devices. Tests for systemic toxicity
- United States Pharmacopeia 39, National Formulary 34, 2016. <151> Pyrogen Test
- United States Pharmacopeia 39, National Formulary 34, 2016. <85> Bacterial Endotoxins Test

Sterilization:
The PeriView FLEX will be delivered in a sterile state and is intended for single patient use only. Sterilization (ethylene oxide) and packaging of the device was validated using the following standards:

- ANSI/AAMI/ISO 11607-1:2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ANSI/AAMI/ISO 11135-1:2014 Sterilization of health-care products – ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

Packaging integrity and performance testing on devices that had undergone accelerated aging support a labeled one year shelf life.

Bench testing:

During design verification testing, the output of the design process was evaluated against the physical and performance specifications. The following performance tests were conducted:

- Sheath and Needle Insertion and Withdrawal Force
- Stylet Insertion and Withdrawal Force
- Bronchoscope Angulation
- Activation Force
- Plastic Deformation Angle
- Puncture Force
- Transmission Force
- Handle Assembly Strength/Handle Durability
- Device Durability
- Vacuum Decay Test

Conclusion:
In summary, the PeriView FLEX is substantially equivalent to the predicate device and presents no new questions of safety or effectiveness.