July 3, 2018

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

Re: K181193
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: June 1, 2018
Received: June 4, 2018

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.

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)*
K181193

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K181193
510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
PeriView 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:	May 3, 2018

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 Device

K171232	Gyrus ACMI, Inc. PeriView FLEX

Comparison to Predicate Device:

The PeriView FLEX has been compared to the predicate PeriView FLEX with respect to intended use, design and fundamental scientific technology. The comparisons and summary of testing results presented in this Special 510(k)

Notification show this device to be substantially equivalent to the predicate PeriView FLEX and raises no new concerns of safety or effectiveness.

Like the predicate PeriView FLEX, the modified PeriView FLEX is intended to be used through a compatible bronchoscope for the collection of tissue from the intrapulmonary regions.

Product Description

The PeriView FLEX needle is a single use tissue biopsy device that consists of five parts: Handle, Stopper, Sheath, Needle, and, Stylet. The sheath and needle (together termed the *insertion section*) are attached to the handle. The Stopper is removable and is attached between the Handle and the Needle Slider. The removable Stylet runs the full length of the device and is located within the inner lumen of the needle.

Technological Characteristics

PeriView FLEX, with the Stopper, is identical in design to its predicate, PeriView FLEX, except for the added Stopper. They both operate similarly to obtain a tissue sample by inserting the insertion section (sheath and needle) of the device into a bronchoscope's working channel or guide sheath. It is then pushed forward to position the device to the tissue target. The Needle is then advanced out of the sheath and into the tissue by pushing the Needle Slider forward while holding the handle. When the Needle Slider is pushed forward (distally), the Needle can be deployed up to 20 mm from the sheath's distal tip. With the Stopper attached between the Handle and the Needle Slider, it blocks the forward movement of the Needle Slider, reducing needle deployment by10mm. The Stopper is removable/replaceable by the user as desired.

Material

No changes were made to patient contacting material or packaging to the modified PeriView FLEX since the predicate system was cleared in K171232.

Intended Uses

The intended use of the modified device, as described in its labeling, has not changed as a result of the addition of the stopper.

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.

Summary of Sterilization and Shelf Life Discussion

Like the predicate PeriView FLEX, (K171232), the modified PeriView FLEX will be distributed in a sterile state and is intended for single patient use only. The sterilization method used continues to be ethylene oxide.

Summary of All Performance Testing (no clinical testing was conducted)

Description	Specification/objective
Stopper Width	Meet width specification
Removal Force	Meet specification
Bubble Leak	ASTM F2096-11
Accelerated Aging	ASTM F1980-16

All performance testing passed or met prescribed acceptance criteria

Substantial Equivalence

The modified PeriView FLEX has the same intended use, scientific technology and similar design as its predicate PeriView FLEX device. The predicate and modified PeriView FLEX devices are both bronchial aspiration needles consisting of a handle, sheath, needle, and stylet. The predicate and modified devices were shown to perform substantially equivalent in bench testing. There were no new issues of safety or effectiveness with the proposed device. Please see the following substantial equivalence comparison table.

	Predicate Device (K171232)	**Proposed Device**
Device Name/ Characteristics	**PeriView FLEX**	**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	Similar A Stopper will be added to the shaft on the piston of the needle assembly.
Patient Contacting	Stainless Steel, PTFE, PeBax™, Nitinol	Identical

	Predicate Device (K171232)	Proposed Device
Device Name/ Characteristics	**PeriView FLEX**	**PeriView FLEX**
Materials		
Biocompatible	Yes	Yes
Sterilization	Ethylene Oxide	Identical
Single Use Only	Yes	Identical
Maximum Working OD (mm)	1.5	Identical
Catheter Length (cm)	115	Identical
Needle Gauge	21G	Identical
Maximum Needle Extended Length (mm)	20	Identical
Stylet OD (mm)	0.47	Identical

Conclusion:

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