March 18, 2020

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

Re: K193517
Trade/Device Name: ViziShot 2 FLEX
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: KTI
Dated: December 18, 2019
Received: December 19, 2019

Dear Mary 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

K193517

Device Name
ViziShot 2 FLEX

Indications for Use *(Describe)*

The ViziShot 2 FLEX has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) 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.

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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:	December 18, 2019

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:	Gyrus ACMI ViziShot 2 FLEX
Generic/Common Name:	Aspiration Needle

Predicate Device

Cook Ireland, Ltd Echotip Procore Endobronchial High Definition Ultrasound Biopsy Needle	K160229

Reference Device

Gyrus ACMI ViziShot 2 FLEX	K163469

Product Description

The subject device, ViziShot 2 FLEX is a single use aspiration needle to be used in conjunction with compatible ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions of the tracheobronchial tree.

The subject 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. The device is a single-use sterile device.

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 2 FLEX is available in one model only (NA-U403SX-4019), with a needle size of 19 gauge (19G). The two required accessories, the Adapter Biopsy Valve and the Merit Syringe with Stopcock, are packaged with the ViziShot 2 FLEX.

Intended Use

The ViziShot 2 FLEX has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions of the tracheobronchial tree. Do not use this device for any purpose other than its intended use.
Comparison of Proposed and Predicate DeviceThe proposed addition of "fine needle biopsy (FNB)" to the Indications for Use is the same as the primary predicate Cook Echotip Procore Endobronchial High Definition Ultrasound Biopsy Needle cleared via K160229.
The ViziShot 2 FLEX has the same technological characteristics and design as the as the reference predicate ViziShot 2 FLEX cleared under K163469. The subject and predicate device operate in the same manner to obtain a tissue biopsy using an ultrasound endoscope. Please refer to the following Substantial Equivalence Table.

Table 5.1 Comparison of Proposed and Predicate Device

		Proposed Device	**Predicate Device (K160229)**	**Reference Device (K163469)**	
Device Name/ Characteristics		**Gyrus ACMI ViziShot 2 FLEX**	**Cook Echotip Procore Endobronchial High Definition Ultrasound Biopsy Needle**	**Gyrus ACMI ViziShot FLEX**	**Comment**
Indications for Use		The ViziShot 2 FLEX has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions of the tracheobronchial tree. Do not use this device for any purpose other than its intended use.	Echotip Procore® Endobronchial High Definition Ultrasound Biopsy Needle for use with Olympus EBUS scopes: This device is used with an ultrasound endoscope for fine needle biopsy, (FNB), of submucosal and extramural lesions within or adjacent to the tracheobronchial tree or gastrointestinal tract.	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.	Similar to the Cook Predicate.
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	Identical
Mechanics of Action		Manual	Manual	**Manual**	Identical
Mode of Action		Single/multiple puncture and aspirate	Single/multiple puncture and aspirate	Single/multiple puncture and aspirate	Identical
General design		Handle, Sheath, Needle, Stylet	Handle, Sheath, Needle, Stylet	Handle, Sheath, Needle, Stylet	Identical
Patient Contacting Materials		Stainless Steel, PTFE, PEBAX, Nitinol	Unknown	Stainless Steel, PTFE, PEBAX, Nitinol	Identical to reference ViziShot 2 FLEX
Biocompatible		Yes	Yes	Yes	Identical
Single Use Only		Yes	Yes	Yes	Identical
Working OD (mm)		2.08	Unknown	2.08	Identical to reference ViziShot 2 FLEX
Catheter Length (cm)		70	Unknown	70	Identical to reference ViziShot 2 FLEX
Needle Gauge		19G	22G, 25G	19G	Identical to

		Proposed Device	Predicate Device (K160229)	Reference Device (K163469)	
Device Name/ Characteristics		**Gyrus ACMI ViziShot 2 FLEX**	**Cook Echotip Procore Endobronchial High Definition Ultrasound Biopsy Needle**	**Gyrus ACMI ViziShot FLEX**	**Comment**
					reference ViziShot 2 FLEX
Typical Needle Length (mm)		20	Unknown	20	Identical to reference ViziShot 2 FLEX
Max Needle Length (mm)		40	Unknown	40	Identical to reference ViziShot 2 FLEX
Stylet OD (in)		0.0204	Unknown	0.0204	Identical to reference ViziShot 2 FLEX
Stylet Surface Finish		Polished	Unknown	Polished	Identical to reference ViziShot 2 FLEX
Accessories		Syringe with stopcock and Adapter biopsy valve are provided with device	Syringe with stopcock and Device adapter/ biopsy valve are provided with device	Syringe with stopcock and Adapter biopsy valve are provided with device	Identical
Packaging		Needle assembly, syringe, adapter placed in tray with snap downs and Tyvek lid. Tray placed in shelf box prior to sterilization.	Needle assembly, syringe, adapter placed in tray with snap downs and lid.	Needle assembly, syringe, adapter placed in tray with snap downs and Tyvek lid. Tray placed in shelf box prior to sterilization.	Identical
Sterilization		EO	EO	EO	Identical
Shelf Life		3 Year at launch	Unknown	1 Year at launch	Reference device subsequent to launch achieved 3 Year Shelf Life

Summary of Perfomance Testing

The proposed ViziShot 2 FLEX in its final finished form is identical to the reference ViziShot 2 FLEX (previously marketed device) in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

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

Biocompatibility testing:

Biocompatibility testing on all patient contacting surfaces has been performed in Accordance with the FDA Guidance Document "*Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".* 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 – Part5: 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

ViziShot 2 FLEX is external communicating, blood path, indirect, and limited duration (<24 hour).

Sterilization/Shelf Life testing:

The ViziShot 2 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 three year shelf life. Accelerated aging tests for the ViziShot 2 FLEX was conducted in accordance with ASTM F1980-16. Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Performance testing – Bench

During design verification, 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
- Penetration Force
- Transmission Force
- Device Durability/Handle Durability
- Bronchoscope Adapter Sliding Force
- Handle Durability
- Sheath to Handle Joint Strength
- Echogenicity

A GLP Comparison of the ViziShot 2 FLEX to the Echotip Procore Endobronchial High Definition Ultrasound Biopsy Needle was performed. The purpose of this study was to evaluate the test article, ViziShot 2 FLEX 19G Needle, and a predicate control article to determine if the needles obtain sufficient tissue samples for histologic and core sample analysis and that the test article needle provided similar quality of samples as the predicate. The performance testing in this study included observations on ease of needle passage through the tissue, and tissue sampling metrics to include weight, length, number of segments and quality of the tissues obtained for microscopic evaluation.

Performance testing – Animal

No animal study was performed to demonstrate substantial equivalence.

Performance testing – Clinical

No clinical study was performed to demonstrate substantial equivalence.

Conclusion:
In summary, the Olympus ViziShot 2 FLEX is substantially equivalent to the predicate devices and presents no new questions of safety or effectiveness.