DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 6, 2017

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

Re: K163469
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: March 9, 2017
Received: March 10, 2017

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. 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,

Tina Kiang -S

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
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) 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.

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 16, 2016

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:	ViziShot 2 FLEX
Generic/Common Name:	Aspiration Needle

Predicate Devices

Spiration, Inc. ViziShot FLEX	K152922

Product Description

The ViziShot 2 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 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) of submucosal and extramural lesions of the tracheobronchial tree. Do not use this device for any purpose other than its intended use**.**

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

Technological Characteristics

The technological characteristics of the ViziShot 2 FLEX are the same as those of the predicate ViziShot FLEX. 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 of Technological Characteristics

The ViziShot 2 FLEX has the same basic technological characteristics as the predicate ViziShot FLEX cleared under K152922. 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 2 FLEX are the same as that of the predicate.

The ViziShot 2 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 the manufacturing assembly more efficient. The resulting device functionality, look, and interaction with the physician are equivalent to those of the predicate device ViziShot FLEX. A detailed comparison of the ViziShot 2 FLEX and the ViziShot FLEX is provided in the following table.

	Predicate Device (K152922)	**Modified Device**
Device Name/ Characteristics	**ViziShot FLEX**	**ViziShot 2 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.	The ViziShot 2 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

	Predicate Device (K152922)	**Modified Device**
Device Name/ Characteristics	**ViziShot FLEX**	**ViziShot 2 FLEX**
Mechanics of Action	Manual	Identical
Mode of Action	Single/multiple puncture and aspirate	Identical
General design	Handle, Sheath, Needle, Stylet	Similar The handle profile design has been changed to improve ergonomics and utilize Design for Manufacturing principles. Changes include: • Handle shape and added rubber finger grip • Sheath adjuster rotates • Snap bonds instead of screw and glue
Patient Contacting Materials	Stainless Steel, PTFE, PEBAX, Nitinol	Stainless Steel, PTFE, PEBAX, Nitinol
Biocompatible	Yes	Yes
Product Specification and Properties	Engineering bench testing confirms that the modified ViziShot 2 FLEX meets its critical product specifications, which are substantially equivalent to those of the predicate ViziShot FLEX.	
Sterilization	EO	EO
Single Use Only	Yes	Identical
Working OD (mm)	2.08	Identical
Catheter Length (cm)	70	Identical
Needle Gauge	19G	Identical
Typical Needle Length (mm)	20	Identical
Max Needle Length (mm)	40	Identical
Stylet OD (in)	0.0205	Equivalent 0.0204
Stylet Surface Finish	Polished	Identical
Accessories	Syringe with stopcock Adapter biopsy valve Devices provided with device	Identical
Packaging	Needle assembly in tray with	Needle assembly, syringe,

	Predicate Device (K152922)	**Modified Device**
Device Name/ Characteristics	**ViziShot FLEX**	**ViziShot 2 FLEX**
	snap downs. Tray placed in pouch. Pouch placed in shelf box (dust cover) for sterilization. After sterilization, the sterile pouched syringe and sterile pouched adapter will be added to the dust cover.	adapter placed in tray with snap downs and tyvek lid. Tray placed in shelf box prior to sterilization.

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 – 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

Sterilization:
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 one year shelf life.

Bench testing:

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

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