Micro-Tech (Nanjing) Co., Ltd.
Sally He
R A Engineer
No. 10 Gaoke Third Road,
Nanjing National Hi-tech Industrial Development Zone
Nanjing, Jiangsu Province 210032
China

Re: K213060
Trade/Device Name: AreusTM Endobronchial Ultrasound Aspiration Needle, TridentTM Endobronchial Ultrasound Aspiration Needle
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: June 17, 2022
Received: June 21, 2022

Dear Sally He:

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,

Brandon Blakely
Assistant Director
DHT1C: Division of 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

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)*

Device Name
Endobronchial Ultrasound Aspiration Needle

Indications for Use *(Describe)*
The Endobronchial Ultrasound Aspiration Needle is used with ultrasound endoscope to sample targeted submucosal and extramural lesions of the tracheobronchial tree.

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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510K Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: **K213060**

1. Sponsor Identification

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, PRC

Establishment Registration Number: 3004837686

Contact Person: Sally He

Position: RA Engineer

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Email: RA.Micro-Tech@outlook.com

2. Identification of Proposed Device

Product Name: Endobronchial Ultrasound Aspiration Needle

Trade Name:

Areus™ Endobronchial Ultrasound Aspiration Needle

Trident™ Endobronchial Ultrasound Aspiration Needle

Common Name: Aspiration Needle

Regulatory Information

Classification Name: Bronchoscope (flexible or rigid) and accessories

Classification: 2

Product Code: KTI

Regulation Number: 874.4680

3. Identification of Predicate Device

Predicate Device :

510(k) Number: K163469

Device Name: Vizishot 2 Flex

Manufacture: Olympus Surgical Technologies America

Reference Device 1:

510(k) Number: K163248, K151895

Device Name: Aquire™ Pulmonary Endobronchial Ultrasound Fine Needle Biopsy (FNB) Device

Manufacture: Boston Scientific Corporation

Note: This reference device is used to as a reference for the FNB needle of proposed device.

Reference Device 2:

510(k) Number: K190239

Device Name: Single Use Aspiration Needle

Manufacture: Olympus Surgical Technologies America

Note: This reference device is used to as a reference for the 25G needle of proposed device.

Reference Device 3:

510(k) Number: K172309

Device Name: Endoscopic Ultrasound Aspiration Needle

Manufacture: Micro-Tech (Nanjing) CO, Ltd.

Note: This reference device is used to as a reference for the selected acceptance criteria of puncture force of proposed device.

4. Indications for Use

The Endobronchial Ultrasound Aspiration Needle is used with ultrasound endoscope to sample targeted submucosal and extramural lesions of the tracheobronchial tree.

5. Device Description

The proposed device Endobronchial Ultrasound Aspiration Needle is a sterile, single-use bronchoscopic device, is designed to sample targeted submucosal and extramural lesions of the tracheobronchial tree.

The Endobronchial Ultrasound Aspiration Needle consists of an Aspiration Needle, Adaptors and Negative suction device (Stopcock and Syringe). Wherein, the Aspiration Needle consists of a handle, sheath, needle, and stylet. The handle is connected to the channel port of a bronchoscope via the proper adaptor. The needle is deployed in the sheath and projected from the sheath to penetrate the target lesion to serve sample by advancement of handle. The stylet is in place in order to provide protection to the inside of the needle tube and sheath during device passage, and also used to expel the sample after the procedure. The adaptors are provided different bronchoscopes with compatibility and attached onto the channel port as the middleware between a bronchoscope and the aspiration needle. The negative suction device is connected to the proximal end of the handle to aspirate the removed tissue.

The Endobronchial Ultrasound Aspiration Needle has echogenic features and is visible under ultrasound at the distal end to facilitate real time visualization of the device under ultrasound.

The proposed device has six models, and the main differences of these models are diameter and tip type of the needle. The Endobronchial Ultrasound Aspiration Needle offers 19G, 22G, 25G needles by size or gauge to respond various clinical options of accessing and sampling. There are two kinds of different tip design (bevel and trident) of needles for FNA (Fine Needle Aspiration) and FNB (Fine Needle Biopsy). The device is identified as is Areus™ Endobronchial Ultrasound Aspiration Needle and Trident™ Endobronchial Ultrasound Aspiration Needle by trade name.

The proposed devices are EO sterilized to achieve the Sterility Assurance Level (SAL) of 10^{-6} and placed in a sterility maintenance package to ensure a shelf life of 3 years.

6. Comparison of Technological Characteristics

The Endobronchial Ultrasound Aspiration Needle incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device **Vizishot 2 Flex (K163469)**.

Comparison to Predicate Devices:

Item	Proposed Device **Endobronchial Ultrasound Aspiration Needle**	Predicate Device **Vizishot 2 Flex (K163469)**	Remark
Product Code	KTI	KTI	Identical
Regulation No.	874.4680	874.4680	Identical
Class	2	2	Identical
Indications for Use	The Endobronchial Ultrasound Aspiration Needle is used with ultrasound endoscope to sample targeted submucosal and extramural lesions of the tracheobronchial tree.	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.	SE
Use Condition	Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope	Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope	SE
Mechanics of Action	Manual	Manual	SE
Mode of Action	Single/multiple puncture and aspirate	Single/multiple puncture and aspirate	SE
General Configuration	➢ Needle Assebly: Handle, Sheath, Needle, Stylet; ➢ Syringe with stopcock ➢ Adapter	➢ Needle Assebly: Handle, Sheath, Needle, Stylet; ➢ Syringe with stopcock ➢ Adapter	SE
Main Materials	PVDF, Nitinol	Stainless Steel, PTFE, PEBAX, Nitinol	Different, the material of proposed device meet the requirement of ISO 10993 series standard
Needle Gauge	19G, 22G, 25G	19G	Different, more options than predicate device. For the different models, reference 1 and reference 2 were used
Needle Diameter /mm	1.1, 0.7, 0.5	1.1	
Needle Tip	Bevel, Trident	Bevel	

Item	Proposed Device **Endobronchial Ultrasound Aspiration Needle**	Predicate Device **Vizishot 2 Flex (K163469)**	Remark
			and the side-by-side comparison testing was conducted to ensure the safety and effectiveness.
Stylet OD (inch)	0.030, 0.016, 0.011	0.020	Different, different needle gauge match different stylet. Note: the Stylet OD of predicate device is tested by us.
Maximum Needle Length /mm	40	40	SE
Working Length /mm	720-760	700	SE
Maximum Insertion Portion Diameter /mm	1.8	2.1	Different, smaller sheath diameter can match smaller endoscopy working channel. More options than predicate device.
Compatible endoscopy working channel	Minimum 2.0mm	Minimum 2.2mm	
Single Use	Yes	Yes	SE
Supplied in Sterile	Yes	Yes	SE
Packaging	Needle assembly, syringe with stopcock and adapter are placed in tray with snap downs. Tray placed in pouch. Pouch placed in case box for sterilization.	Needle assembly in tray with 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.	Different, the packaging of proposed device have passed the packaging validation according to ISO 11607-1 and ISO 11607-2

Item	Proposed Device **Endobronchial Ultrasound Aspiration Needle**	Predicate Device **Vizishot 2 Flex (K163469)**	Remark
Shelf Life	Three years	Three years	SE
Biocompatibility	Conform to ISO 10993-1	Conform to ISO 10993-1	SE
Sterilization	EO Sterilized, SAL:10^{-6}	EO Sterilized, SAL:10^{-6}	SE
Labeling	Conform to 21 CFR part 801	Conform to 21 CFR part 801	SE

The proposed device is similar in design to Vizishot 2 Flex, the main needle diameter and needle tip of proposed device are different to that of predicate device. For the difference, two reference devices (Aquire™ Pulmonary Endobronchial Ultrasound Fine Needle Biopsy (FNB) Device from Boston Scientific Corporation and Single Use Aspiration Needle from Olympus Surgical Technologies America) was selected. All comparative nonclinical performance testing have been tested and have met the requirements of substantial equivalence to the predicate device/reference device.

Therefore, the difference between proposed device and predicated device is considered not to affect the substantially equivalency between the proposed and predicate devices concerning the safety and effectiveness.

7. Performance Data

The biocompatibility evaluation for the Endobronchial Ultrasound Aspiration Needle was conducted in accordance with FDA Guidance, Use of International Standard ISO-10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" issued on September 4, 2020, the following tests were conducted:

a) Cytotoxicity

b) Sensitization

c) Irritation

d) Acute System Toxicity

e) Pyrogen

f) Hemocompatibility (Hemolysis, thrombogenicity and complement activation testing)

Sterilization validation of Endobronchial Ultrasound Aspiration Needle was carried out in accordance with ISO 11135:2014+A1:2018 “Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”.

Shelf-life testing and packaging integrity testing of Endobronchial Ultrasound Aspiration Needle was conducted based on an accelerated aging test in accordance with ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices and ISO 11607-1:2019: Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems and ISO 11607-2:2019: Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes. Three-years accelerated aging test have been performed to demonstrate the stability during the shelf life.

During design verification, the following bench tests were performed on Endobronchial Ultrasound Aspiration Needle:

- Dimension;
- Sheath and Needle Insertion and Withdrawal force;
- Stylet Insertion and Withdrawal Force;
- Puncture Force;
- Ultrasound Visibility;
- Locking Force of Handle Portion;
- Adjustment Length;
- Attach and Detach Adaptor to Scope;
- Tensile Strength;
- Durability;
- Aspiration Capability.
- Transmission Force
- Needle Deformation Angle

The results of all the performance testing demonstrated that the proposed device met the predetermined

acceptance criteria and is substantial equivalence to the predicate device Vizishot 2 Flex.

8. Animal Test Conclusion

No animal study is included in this submission.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the **Endobronchial Ultrasound Aspiration Needle** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device **Vizishot 2 Flex (K163469).**