



December 10, 2019

Olympus Medical Systems Corp.
% Daphney Germain-Kolawole
Senior Project Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway
PO Box 610
Center Valley, Pennsylvania 18034-0610

Re: K190239

Trade/Device Name: Single Use Aspiration Needle
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: November 25, 2019
Received: November 26, 2019

Dear Daphney Germain-Kolawole:

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,

for 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

Enclosure

Indications for Use

510(k) Number (if known)

K190239

Device Name

Single Use Aspiration Needle

Indications for Use (Describe)

This instrument 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.

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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November 25, 2019

510(k) Summary

1 GENERAL INFORMATION

- 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
192-8507
- Contact Person: Lisa M. Boyle
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2 DEVICE IDENTIFICATION

- Device Name Single Use Aspiration Needle
- Model Name NA-U401SX-4025N
- Common Name Aspiration Needle
- Regulation Number 21 CFR 874.4680
- Regulation Name Bronchoscope (flexible or rigid) and accessories
- Regulatory Class II
- Product Code KTI
- Classification Panel Ear Nose & Throat

3 PREDICATE DEVICE

■ Predicate device

Device name	510(k) Submitter	510(k) No.
ViziShot 2 FLEX (NA-U403SX-4019)	Olympus Surgical Technologies America	K163469

■ Reference device

Device name	510(k) Submitter	510(k) No.
Single Use Aspiration Needle NA-U401SX	OLYMPUS MEDICAL SYSTEMS CORP.	K160098
Echotip Ultra Endobronchial High Definition Ultrasound Needle, Echotip Procore Endobronchial High Definition Ultrasound Biopsy Needle	Cook Ireland Ltd.	K160229

4 DEVICE DESCRIPTION

■ General Description of the subject device

The Single Use Aspiration Needle NA-U401SX-4025N (aka ViziShot 2) is used in conjunction with Olympus ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA).

The subject devices consist of a handle section and insertion section. The handle section is connected to the endoscope's instrument channel port via the single use adapter biopsy valve (MAJ-1414). The insertion section is composed of the sheath, needle and stylet. The needle tube is stored in the sheath and extended from the sheath to puncture the target tissue to collect specimen by moving the needle slider on the handle. A syringe is attached to the aspiration port on the handle section to aspirate the specimen. The needle is dimpled for echo enhancement.

The subject devices will be sold with or without the medallion syringe manufactured by Merit Medical, which consists of the VACLOK Syringe and Stopcock.

■ Principle of Operation

Ultrasound emitted by the ultrasound transducer of the ultrasound endoscope diffusely reflects at dimples on the echo-enhanced region of the needle tube.

The ultrasound transducer detects the part of the ultrasound which diffusely reflects and the echo-enhanced region is indicated on an ultrasound image.

The needle tube and stylet are extracted from the sheath by moving the needle slider to the distal side and is drawn into the sheath by moving the needle slider in the counter direction.

The subject devices are used with specified ultrasound endoscopes for aspirating tissue or cells by piercing the target area in an ultrasound image and attaching the medallion syringe to the aspiration port on the handle section.

5 INDICATIONS FOR USE

This instrument 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.

6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The Single Use Aspiration Needle NA-U401SX-4025N has the same technological characteristics and design as the predicate device except for the following new features:

- Needle width
- Needle shape
- Needle tip shape
- Sheath composition

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

A side by side comparison of the subject device and the predicate device is provided below.

Item	Subject Device	Predicate Device (PD)
	NA-U401SX-4025N	NA-U403SX-4019 (K163469)
Indications for Use	This instrument 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. Similar to PD	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.
Regulation Number	Identical	874.4680
Regulation Name	Identical	Bronchoscope (flexible or rigid) and accessories
Regulatory Class	Identical	II
Product Code	Identical	KTI
Classification Panel	Identical	Ear Nose & Throat
Syringe (for aspiration)	Identical	Equipped
Mode of action	Identical	Single/multiple puncture and aspirate
Energy used	Identical	Manual
Visualization	Identical	Ultrasound guided
Product Specification and Properties	Bench testing confirms that the NA-U401SX-4025N meets its essential performances, which are technologically equivalent to those of the reference device.	
Reprocessing	Identical	Single Use, ETO Sterile
Needle Width	25G	19G
Patient Contacting Materials Outer sheath	Polytetrafluoroethylene, Stainless Steel, Nickel titanium	Stainless Steel, PTFE, PEBAX, Nitinol

7 PERFORMANCE DATA

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

1) Sterilization/Shelf-life testing

Sterilization/shelf-life testing for the Single Use Aspiration Needle NA-U401SX-4025N was conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile".

Accelerated aging test for the NA-U401SX-4025N was conducted in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices. The real-time aging test for three years will be performed to demonstrate longer stability and support the results of the accelerated aging test.

2) Biocompatibility testing

Biocompatibility testing for the Single Use Aspiration Needle NA-U401SX-4025N was conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1:2009, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The following tests were completed:

- Cytotoxicity
- Intracutaneous Study
- Sensitization
- Systemic Toxicity
- Pyrogen Study

3) Performance testing - Bench

Bench testing for the Single Use Aspiration Needle NA-U401SX-4025N as listed below was conducted to ensure that the subject devices perform as intended and meet design specifications.

- Piercing
- Ultrasound visibility
- Needle extraction and retraction
- Aspiration
- Endoscope compatibility
- Handle function
- Joint Pull Strength
- Breakage Strength

4) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

5) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

6) Risk analysis

A Risk analysis for the Single Use Aspiration Needle NA-U401SX-4025N was conducted in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The following standards have been applied to the Single Use Aspiration Needle NA-U401SX-4025N.

- ISO 10993-1: 2009
- AAMI/ANSI/ISO 10993-5: 2009
- ISO 10993-10: 2010
- ISO 10993-11: 2006
- ISO 11135: 2014
- ISO 10993-7: 2008+Cor1
- ISO 11607-1: 2006+A1
- ISO 11607-2: 2006+A1
- ASTM F1980-16
- ISO 14971: 2007

8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the NA-U401SX-4025N raise no new issue of safety and effectiveness. Therefore, the NA-U401SX-4025N is substantially equivalent to the predicate devices.