November 15, 2018

Olympus Medical Systems Corp.
% Sheri L. Musgnung
Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway P.O. Box 610
Center Valley, PA 18034-0610

Re: K180668
Trade/Device Name: Single Use Aspiration Needle NA-U401SX-4025/NA-U401SX-4025N
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCG
Dated: October 11, 2018
Received: October 15, 2018

Dear Sheri L. Musgnung:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*

K180668

Device Name
Single Use Aspiration Needle NA-U401SX-4025/NA-U401SX-4025N

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 gastrointestinal tract.

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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October 10, 2018

5. 510(k) Summary

5.1 GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
192-8507

■ Contact Person: Sheri L. Musgnung
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-3147
Fax: 484-896-7128
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5.2 DEVICE IDENTIFICATION

■ Device Name	Single Use Aspiration Needle
■ Model Name	NA-U401SX-4025, NA-U401SX-4025N
■ Common Name	Aspiration Needle
■ Regulation Number	21 CFR 876.1075
■ Regulation Name	Gastroenterology-urology biopsy instrument
■ Regulatory Class	II
■ Product Code	FCG
■ Classification Panel	Gastroenterology/Urology

5.3 PREDICATE DEVICE

1) Predicate device

Table 12-1 Primary predicate device for NA-U401SX-4025/NA-U401SX-4025N

Device name	510(k) Submitter	510(k) No.
NA-U401SX-4022 (Single Use Aspiration Needle NA-U401SX)	OLYMPUS MEDICAL SYSTEMS CORP.	K160098

2) Reference device

Table 12-2 **Reference device** for NA-U401SX-4025/NA-U401SX-4025N

Device name	510(k) Submitter	510(k) No.
ECHO-HD-25-EBUS-O (Echotip Ultra Endobronchial High Definition Ultrasound Biopsy Needle)	Cook Ireland Ltd.	K160229

5.4 DEVICE DESCRIPTION

1) General Description of the subject device

The Single Use Aspiration Needle NA-U401SX-4025/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 medallion syringe manufactured by Merit Medical, which consists of VACLOK Syringe and Stopcock.

2) Principle of Operation

Ultrasound emitted by ultrasound transducer of ultrasound endoscope diffusely reflects at dimples on the echo-enhanced region of needle tube.
The ultrasound transducer detects the part of ultrasound which diffusely reflects and the echo-enhanced region is indicated on ultrasound image.

The needle tube and stylet are extracted from the sheath by moving the needle slider to 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 ultrasound image and attaching the medallion syringe to the aspiration port on the handle section.

5.5 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 gastrointestinal tract.

5.6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The Single Use Aspiration Needles, NA-U401SX-4025/NA-U401SX-4025N have 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
- New colored sheath (NA-U401SX-4025 only)

All other technological characteristics of both the subject and predicate devices are identical.

5.7 PERFORMANCE DATA

The following performance data were 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-4025/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-4025/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-4025/NA-U401SX-4025N were 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".

3) **Performance testing - Bench**

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

- Inserting into endoscope
- Flexibility of the insertion portion
- Piercing
- Ultrasound visibility
- Needle extraction and retraction
- Aspiration
- Withdrawal from endoscope
- Locking force of handle portion
- Limitation of needle depth

4) Risk analysis

Risk analysis for the Single Use Aspiration Needle, NA-U401SX-4025/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-4025/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

5.8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the NA-U401SX-4025/ NA-U401SX-4025N raise no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, efficacy and performance.