June 8, 2018

Olympus Medical Systems Corp.
Sheri L. Musgnung
Regulatory Affairs Manager
3500 Corporate Parkway
Center Valley, PA 18034

Re: K180449
Trade/Device Name: Single Use Aspiration Needle NA-U200H
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCG
Dated: April 27, 2018
Received: April 30, 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. 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.

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.

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,

Benjamin R. Fisher -S

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)*

K180449

Device Name
Single Use Aspiration Needle NA-U200H

Indications for Use *(Describe)*

This instrument has been designed to be used with an Olympus ultrasound endoscope for ultrasonically guided fine needle aspiration(FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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February 16, 2018

Section 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
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5.2 DEVICE IDENTIFICATION

■ Device Name: Single Use Aspiration Needle NA-U200H

■ 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 and Urology

5.3 PREDICATE DEVICE

1) Primary predicate device

Table 12-1 Primary predicate device on Single Use Aspiration Needle NA-U200H

Device name	510(k) Submitter	510(k) No.
Single Use Aspiration Needle NA-U200H	OLYMPUS MEDICAL SYSTEMS CORP.	K151738

2) Reference device

Table 12-2 Reference device on Single Use Aspiration Needle NA-U200H

Device name	510(k) Submitter	510(k) No.
Echotip Procore HD Ultrasound Biopsy Needle	COOK IRELAND LTD	K142688

5.4 DEVICE DESCRIPTION

The subject devices are single use aspiration needles to be used in conjunction with an Olympus ultrasound endoscope for ultrasonically guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes).

The subject devices consist of a handle section, needle section, and sheath section and needle sizes ranging from 19 to 25G are available. The subject devices are sterilized and packaged in a sterilization package. The Syringe (VACLOK Syringe and Stopcock), which is supplied by Merit Medical System and packaged in an individual sterilization package, is bundled. The subject devices and the Syringe are put in one carton. When users use the device, the syringe is attached to the aspiration port on the handle section of the subject devices.

5.5 INDICATIONS FOR USE

This instrument has been designed to be used with an Olympus ultrasound endoscope for ultrasonically guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes).

5.6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The Single Use Aspiration Needle NA-U200H has the same technological characteristics and design as the predicate device except for expanding the indications for use and adding a new 25G needle to a family of needles. The fundamental technology remain unchanged and the performance of new 25G needle was demonstrated by conducting tests simulating ultrasonically guided fine needle aspiration (FNA) or fine needle biopsy (FNB).

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-U200H were 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 demonstrating stability of the Single Use Aspiration Needle NA-U200H 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-U200H were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

3) Performance testing - Bench

Bench testing has been performed on the proposed Single Use Aspiration Needle NA-U200H.Bench Testing includes:

1. Inserting into endoscope
2. Advance of needle
3. Retreat of stylet
4. Visibility of needle
5. Aspiration by syringe
6. Retreat of needle
7. Withdrawal from endoscope
8. Extracting specimen from the needle by feeding air using a syringe
9. Extracting specimen from the needle by advancing a stylet
10. Repetition test
11. Needle durability
12. Package integrated test
13. Comparison of tissue sampling

4) Performance testing - Animal

This premarket notification does not rely on Animal study data to demonstrate substantial equivalence.

5) Performance testing - Clinical

This premarket notification does not rely on clinical study data to demonstrate substantial equivalence.

6) Risk analysis

Risk analysis for the Single Use Aspiration Needle NA-U200H 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.

5.8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the Single Use Aspiration Needle NA-U200H raise no new issue of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, efficacy and performance.