October 31, 2018

Olympus Medical Systems Corp.
% Mary Anne Patella
Senior Specialist, Regulatory Affairs
Olympus Surgical Technologies America
136 Turnpike Road
Southborough, MA 01772

Re: K181994
Trade/Device Name: Single Use Aspiration Needle NA-U201H
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCG
Dated: October 3, 2018
Received: October 4, 2018

Dear Mary Anne 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. 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,

Jeffrey W. Cooper -S
2018.10.31 16:45:48 -04'00'

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)*
K181994

Device Name
Single Use Aspiration Needle NA-U201H

Indications for Use *(Describe)*
These instruments have been designed to be used with an Olympus ultrasound endoscope for ultrasonically guided fine needle aspiration (FNA) 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

July 23, 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: Mary Anne Patella
Olympus Surgical Technologies America
136 Turnpike Road
Southborough, MA 01772, USA
Phone: 508-804-2771
Fax: 508-804-2624
Email: Maryanne.patella@olympus-osta.com

5.2 DEVICE IDENTIFICATION

■ Device Name: Single Use Aspiration Needle NA-U201H

■ 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-U201H

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-U201H

Device name	510(k) Submitter	510(k) No.
DISPOSABLE ASPIRATION NEEDLE NA-200H	OLYMPUS MEDICAL SYSTEMS CORP.	K023272
EXPECT ENDOSCOPIC ULTRASOUND ASPIRATION NEEDLE	BOSTON SCIENTIFIC CORP.	K110030

5.4 DEVICE DESCRIPTION

The Single Use Aspiration Needle NA U201H are single use aspiration needles to be used in conjunction with an Olympus ultrasound endoscope for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes).

The Single Use Aspiration Needle NA U201H consist of a handle section, needle section, and sheath section and needle sizes ranging from 19 to 25G will be available. The Single Use Aspiration Needle NA U201H 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 Single Use Aspiration Needle NA U201H 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

These instruments have been designed to be used with an Olympus ultrasound endoscope for ultrasonically guided fine needle aspiration (FNA) 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-U201H has the same technological characteristics and design as the predicate device except for following features:

- Needle width (addition of 25G needle)
- Maximum insertion portion diameter (smaller diameter)
- Patient-contacting material (sheath, needle, silicone oil)
- Stylet diameter (smaller diameter for 25G needle)
- Tip shape of needle (Backcut, Lancet shape)
- Sheath type

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

Table 12-3 A side by side comparison of the subject device and the predicate device

Item	Subject Device Single Use Aspiration Needle NA-U201H	Predicate Device Single Use Aspiration Needle NA-U200H (K151738)
Indications for use	These instruments have been designed to be used with an Olympus ultrasound endoscope for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes).	This instrument has been designed to be used with an Olympus ultrasound endoscope for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes).
Common name	Aspiration Needle	Aspiration Needle
ra	876.1075	876.1075

Item	Subject Device Single Use Aspiration Needle NA-U201H	Predicate Device Single Use Aspiration Needle NA-U200H (K151738)
Regulation name	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument
Regulatory class	II	II
Classification panel	Gastroenterology and Urology	Gastroenterology and Urology
Product code	FCG	FCG
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital
Single/repeat use	Single-Use	Single-Use
Sterile/non-sterile	Marketed as a sterile device	Marketed as a sterile device
Sterilization method	ETO sterile	ETO sterile
Patient-contact materials	Sheath: PEEK Needle: Stainless steel Stylet: Nitinol Silicone oil: Methylphenyl Polysiloxane	Sheath: Stainless steel Needle: Nitinol and Stainless steel Stylet: Nitinol Silicone oil: Not equipped

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-U201H 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-U201H 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-U201H 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-U201H.Bench Testing includes:

- Insertion and withdrawal performance
- Visibility by using diagnostic ultrasound systems
- Aspiration performance
- Needle durability and package integrated test

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-U201H 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-U201H raises no new issues of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, effectiveness and performance.