DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 20, 2015

Olympus Medical Systems Corp.
% Daphney Germain-Kolawole
Project Manager, Regulatory Affairs
Olympus Corporation of The Americas
3500 Corporate Parkway
Po Box 610
Center Valley, PA 18034-0610

Re: K151738
Trade/Device Name: Single Use Aspiration Needle NA-U200H
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: FCG
Dated: October 19, 2015
Received: October 20, 2015

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151738

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) 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) SUMMARY
Single Use Aspiration Needle NA-U200H

June 25, 2015

5.1 General Information

■ Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Establishment Registration No: 8010047
■ Official Correspondent:	Daphney Germain-Kolawole Olympus Corporation of the Americas, Inc. 3500 Corporate Parkway PO Box 610 Center Valley, PA 18034-0610, USA Phone: 484-896-5691 FAX: 484-896-7128 Email: daphney.germain-kolawole@olympus.com
■ Manufacturer:	Aomori Olympus Co., Ltd. 248-1 Okkonoki 2-chome Kuroishi-shi, Aomori, Japan 036-0357 Establishment Registration No.: 9614641

5.2 Device Identification

■ Device Trade Name:	Single Use Aspiration Needle NA-U200H
■ Common Name:	Aspiration Needle
■ Regulation Number:	876.1075
■ Regulation Name:	Gastroenterology-urology biopsy instrument
■ Regulatory Class:	II
■ Classification Panel:	Gastroenterology and urology
■ Product Code:	FCG

5.3 Predicate Device Information

Device Trade Name	Common Name	Applicant	510(k) No.
Disposable Aspiration Needle NA-200H	Aspiration Needle	OLYMPUS OPTICAL Co., Ltd.	K023272
Olympus NA-10J-1 Aspiration Needle	Biopsy Instruments	OLYMPUS AMERICA, INC.	K973128
Expect™ Endoscopic Aspiration Needle	-	BOSTON SCIENTIFIC CORPORATION	K112198

5.4 Device Description

The subject device is a Single Use Aspiration Needle NA-U200H 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).

The subject device consists of a handle section, needle section, and sheath section. When users use the device, the syringe needs to be attached to the subject device. The subject device is used to obtain an acceptable specimen. The lesion is punctured by the Needle equipped at the distal end of the subject device and aspirated by the syringe. Subsequently, the tissue of the lesion in the needle is taken out by feeding air from the syringe or pushing the tissue with the stylet for sampling.

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) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal

masses and lymph nodes).

5.6 Comparison of Technological Characteristics

Compared to the predicate device, the proposed subject device, Single Use Aspiration Needle NA-U200H, has similar technological characteristics. There is no significant difference that affects the safety or effectiveness of the subject device.

5.7 Summary of non-clinical testing

·Performance testing was conducted to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.

·Risk analysis was carried out 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.

·Biocompatibility testing is performed in accordance with the FDA Guidance," Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, Blue Book Memo, G95-1".

The following standards have been applied to the Single Use Aspiration Needle NA-U200H.

·ISO 10993-1
·ISO 10993-5
·ISO 10993-10
· ISO 10993-11
·ISO 11135
·ISO 14971
·ASTM F1980-07

5.8 Conclusion

When compared to the predicate device, the Single Use Aspiration Needle NA-U200H does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.