August 2, 2019

Olympus Medical Systems Corp.
% Jonathan Gilbert
Regulatory Affairs Consultant to OCA
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, Pennsylvania 18034-0610

Re: K190293
Trade/Device Name: Single Use Cytology Brush BC-205D
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: BTG
Dated: July 2, 2019
Received: July 3, 2019

Dear Jonathan Gilbert:

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,

James 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

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)*

K190293

Device Name

Single Use Cytology Brush BC-205D

Indications for Use *(Describe)*

- Single Use Cytology Brush BC-205D

The cytology brush has been specifically designed to collect specimens or cells endoscopically for cytologic examination in conjunction with Olympus bronchoscopes with channel φ1.7mm or larger .

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 Cytology Brush BC-205D

July 30, 2019

5.1 General Information

■ Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Establishment Registration No: 8010047
■ Official Correspondent:	Jon Gilbert fbo Daphney Germain-Kolawole Olympus Corporation of the Americas 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 and Model number (if applicable):	Single Use Cytology Brush BC-205D (Model number: BC-205D-2010)
■ Common Name:	Single Use Cytology Brush
■ Regulation Number:	874.4680
■ Regulation Name:	Bronchoscope (flexible or rigid) and accessories
■ Regulatory Class:	II
■ Classification Panel:	Ear Nose & Throat
■ Product Code:	BTG; Brush, biopsy, bronchoscope (non-rigid)

5.3 Predicate Device/Reference Device Information

	K number	Product name	Manufacturer
Predicate device	K780872	CYTOLOGY BRUSH	COOPERVISION, INC.
Reference device	K171607	Bronchi and Gastrointestinal Cytology Brush	Wilson-Cook Medical, Inc. / Cook Endoscopy

5.4 Device Description

The single use cytology brush BC-205D has been designed to collect specimens or cells endoscopically for cytologic examination in conjunction with bronchoscopes.

Identical to the predicate device, the subject device is inserted into bronchoscope channel to collect specimens with the brush which is equipped at the distal end of the subject device. Then users withdraw the subject device from bronchoscope channel and collect samples for cytology examination.

5.5 Indications for Use

The cytology brush has been specifically designed to collect specimens or cells endoscopically for cytologic examination in conjunction with Olympus bronchoscopes with channel ϕ1.7mm or larger.

5.6 Comparison of Technological Characteristics

Compared to the predicate device, our subject device, Single Use Cytology Brush BC-205D, mainly has the following technical differences:

1) Configuration of the device
2) Compatible endoscope
3) Material of the device

Validation from the non-clinical testing supported the substantial equivalence of the subject device with the predicate device

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

Features	Subject device Single Use Cytology Brush BC-205D	Predicate device (PD) Cytology Brush
Administrative information		
510(k)	Not yet known	K780872
Regulation number	Same as PD	874.4680
Device class	Same as PD	II
Product code	Same as PD	BTG
Indications for use		
Indications for use	The cytology brush has been specifically designed to collect specimens or cells endoscopically for cytologic examination in conjunction with Olympus bronchoscopes with channel ϕ1.7mm or larger.	The device is intended to be used through endoscopes for the purpose of collecting sterile, non-contaminated specimens for microbiological analysis.
Technology features		
Compatible endoscopes	Olympus bronchoscopes with channel ϕ1.7mm or larger.	Bronchoscope
Sterile status	Same as PD	Sterile product
Maximum insertion portion diameter	ϕ 1.4 mm	ϕ 1.8 mm
Working length	1150mm	900mm
Brush diameter	ϕ 2 mm	ϕ 1 mm
Brush length	10mm	N/A
Material	Tube: single-layer high density polymer Plug: none Distal tip/Wire: stainless steel Brush: nylon	Tube: two-layer Teflon catheter Plug: non-toxic water soluble wax Distal tip/Wire: N/A Brush: N/A

5.7 Summary of non-clinical testing

The technological differences between the predicate device and the subject device have been verified and validated by means of the following tests and standards to endorse the claims of substantial equivalence to the predicate device.

•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 was performed in accordance with the FDA Guidance, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" issued on June 16 2016.

•Sterilization validation and Shelf-life testing
Sterilization validation was carried out with the method of Half-cycle approach in accordance with ISO 11135:2014. The shelf-life for three years has been validated by accelerated testing according to ASTM F1980-16. The requirements on packaging for terminally sterilized medical device per AAMI/ANSI/ISO 11607-1/2 have also been validated.

•Performance testing
The following bench tests were also carried out to demonstrate the performance of the subject device.
1) Brush operation with the compatible endoscope
2) Dimension of each part of the brush
3) General durability
4) Joint/tensile strength
5) Package integrity

The following standards have been applied to the subject devices.

Standard No.	Standard Title
ISO 14971 Second Edition: 2007-03-01	Medical Devices - Application Of Risk Management To Medical Devices
ISO 10993-1 Fourth Edition:2009-10-15	Biological Evaluation Of Medical Devices - Part1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)]
ISO10993-5 Third Edition: 2009-06-01	Biological Evaluation Of Medical Devices – Part5: Tests For In Vitro Cytotoxicity
ISO 10993-10 Third Edition: 2010-08-01	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
ISO 10993-7:2008 (R)2012	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

Standard No.	Standard Title
-ISO 10993-11 -ASTM F756 -ISO 10993-4 -USP General Chapter <151> -USP 42, NF 37, General Chapters <85> & <161>	-Biological evaluation of medical devices - Part 11: Tests for systemic toxicity -Standard Practice for Assessment of Hemolytic Properties of Materials -Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood -Pyrogen Test -Kinetic-Chromogenic Limulus Amebocyte Lysate test method based on standards
ISO 11135 Second Edition 2014	Sterilization Of Health-Care Products: Ethylene Oxide – Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices.
ASTM F1980-16	Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices
AAMI/ANSI/ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]
AAMI/ANSI/ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)]

5.8 Conclusion

The Single Use Cytology Brush BC-205D is substantially equivalent to the predicate device.