March 6, 2020

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: K192164
Trade/Device Name: Single Use Guide Sheath Kit K-401, K-402, Single Use Guiding Device CC-220DR
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ, BTG
Dated: January 31, 2020
Received: February 3, 2020

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,

for James J. 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)*
K192164

Device Name
Single Use Guide Sheath Kit K-401, K-402 & Single Use Guiding Device CC-220DR

Indications for Use *(Describe)*

Single Use Guide Sheath Kit K-401, K-402

These instruments have been designed to be used with Olympus bronchoscopes, EndoTherapy accessories, and/or ultrasonic probes to guide the EndoTherapy accessories and/or the ultrasonic probes to the target area within the tracheobronchial tree and collect tissue, specimens, or cells bronchoscopically. This kit and its components are intended for adult patients only.

- Indications for use of each component

Single Use Guide Sheath SG-400C
The single use guide sheath has been designed to be used with Olympus bronchoscopes, EndoTherapy accessories, and/or ultrasonic probes to guide the EndoTherapy accessories and/or the ultrasonic probes to the target area within the tracheobronchial tree.

Single Use Biopsy Forceps FB-433D
The biopsy forceps has been designed specifically to collect tissue endoscopically for examination in conjunction with a flexible bronchoscope within the tracheobronchial tree.

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 the bronchoscope within the tracheobronchial tree.

Single Use Guiding Device CC-220DR
This instrument has been designed to be used with an Olympus endoscope and guide sheath to guide the guide sheath to the respiratory organs and to collect specimens within the respiratory organs.
This device is intended for adult patients only.

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.

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Single Use Guide Sheath Kit
& Single Use Guiding Device CC-220DR

March 5, 2020

1. General Information

■ 510(k) submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
Establishment Registration No: 8010047

■ Contact Person: Jon Gilbert fbo Sheri Musgnung.
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Center Valley, PA 18034-0610, USA
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■ Manufacturing site: Aomori Olympus Co., Ltd.
2-248-1 Okkonoki, Kuroishi-shi, Aomori, 036-0357, Japan
Establishment Registration No.: 9614691

2. Device Identification

■ Device Trade Name: Single Use Guide Sheath Kit K-401, K-402

[Component]

- Single Use Guide Sheath SG-400C
- Single Use Biopsy Forceps FB-433D

- Single Use Cytology Brush BC-205D
<Accessory>
ET Stopper / US Stopper
& Single Use Guiding Device CC-220DR

■ Common Name: Guide Sheath Kit & Guiding Device

■ Regulation Number: 874.4680

■ Regulation Name: Bronchoscope (flexible or rigid) and accessories

■ Regulatory Class: II

■ Classification Panel: Ear Nose & Throat

■ Product Code: EOQ , BTG

3. Predicate Device Information

Predicate device for Single Use Guide Sheath SG-400C

■ Device Name: Olympus Guide Sheath, XBO1-836-13

■ Common Name: Bronchoscope accessory

■ Applicant Olympus Medical System Corporation

■ 510(k) No. K060243

Predicate device for Single Use Biopsy Forceps FB-433D

■ Device Name: Single Use Biopsy Forceps FB-433D

■ Common Name: Biopsy forceps

■ Applicant Olympus Medical Systems Corp.

■ 510(k) No. K172726

Predicate device for Single Use Cytology Brush BC-205D

■ Device Name: Single Use Cytology Brush BC-205D

■ Common Name: Cytology brush

■ Applicant Olympus Medical Systems Corp.

■ 510(k) No. K190293

Predicate device for Single Use Guiding Device CC-220DR

■ Device Name: CC-4CR-1 Curette (Double-hinged type)

■ Common Name: Curette

■ Applicant Olympus Medical Systems Corp.

■ 510(k) No. K060243

4. Device Description

Single Use Guide Sheath Kit K-401/K-402

The kit has been designed to be used with Olympus bronchoscopes, EndoTherapy accessories, and/or ultrasonic probes to guide the EndoTherapy accessories and/or the ultrasonic probes to the target area within the tracheobronchial tree and collect tissue, specimens, or cells bronchoscopically.

The compatible bronchoscope for the subject Single Use Guide Sheath Kit needs to have the working length 600mm or less (exclude the ultrasonic bronchoscope) and a working channel inner diameter that is no less than 2.0mm.

The guide sheath kit consists of the following components: Guide Sheath, Biopsy Forceps, with/without Cytology Brush. EU stoppers and US Stopper are also included in the kit as accessories. Each component and the accessory stoppers are sterile and packaged in individual package. All of them are collected into one carton box as one final kit product. Please refer to **Table 1** below.

Table 1 Configuration of Each Kit Model and Components/Accessories in each kit*

Kit Model	K-401	K-402
Guide Sheath	SG-400C	
Biopsy Forceps	FB-433D	
Cytology Brush	BC-205D-2010	NA
ET Stopper Color: White	Quantity: 4	Quantity: 3
US Stopper Color: Dark gray	Quantity: 1	Quantity: 1

*Note: The Guiding Device CC-220DR is not part of either kit model but is to be used with the subject guide sheath, and will be sold separately from the kits.

<Single Use Guide Sheath SG-400C>

The single use guide sheath has been designed to be used with Olympus bronchoscopes, EndoTherapy accessories, and/or ultrasonic probes to guide the EndoTherapy accessories and/or the ultrasonic probes to the target area within the tracheobronchial tree.

This guide sheath is designed to function as an extended working channel. The function of the subject guide sheath is to facilitate obtaining multiple biopsy specimens by leaving the guide sheath in place after localization of the target tissue.

This instrument consists of an insertion portion and a handle portion. The insertion portion is composed of tube and X-ray tip.

<Single Use Biopsy Forceps FB-433D>

The biopsy forceps has been designed specifically to collect tissue endoscopically for examination in conjunction with a flexible bronchoscope. The subject device is allowed to insert into the channel of a bronchoscope with the subject device guide sheath, and then collect tissue with the pair of forceps which is equipped at the distal end of the subject device. Finally, users withdraw the subject device biopsy forceps from the bronchoscope to collect the samples.

<Single Use Cytology Brush BC-205D>

The single use cytology brush BC-205D has been designed to collect specimens or cells endoscopically for cytology examination in conjunction with bronchoscopes.
The subject device is allowed to insert into the channel of a bronchoscope with the subject device guide sheath, and then collect specimens or cells with the brush which is affixed in the distal end of the subject device. Finally, users withdraw the subject device cytology brush from the bronchoscope to collect the samples.

< ET/US Stopper>

The ET stopper and US stopper are included in the guide sheath kit as accessory. They are used to fasten the sampling devices (EndoTherapy accessories) or ultrasonic probe to the guide sheath, which serve as a mark to keep the sampling devices or ultrasonic probe in relative position to the guide sheath. The ET stopper and US stopper are made of silicone rubber outside, molded with stainless steel plate inside.

Single Use Guiding Device CC-220DR

The Single Use Guiding Device has been designed to be used with an Olympus

endoscope and guide sheath to guide the guide sheath to the respiratory organs and to collect specimens within the respiratory organs.

The compatible bronchoscope for the subject Single Use Guiding Device CC-220DR needs to have the working length 600mm or less (exclude the ultrasonic bronchoscope) and a working channel inner diameter that is no less than 2.0mm.

The subject device consists of a handle section and an insertion section. The distal end in the insertion portion consists of a double-joint curette which bends by operating the handle section. The rotation grip in handle section also allows for rotation of the curette in the distal end. The subject device inserts into an endoscope with the guide sheath, and enables the guide sheath to be directed to the target area following the direction the curette in distal end to the target area. The curette can also collect the specimen by scraping the tissue.

Although this device is used together with the subject device guide sheath in Single Use Guide Sheath Kit, it is marketed independently as a single product.

5. Indications for Use

Single Use Guide Sheath Kit K-401, K-402

These instruments have been designed to be used with Olympus bronchoscopes, EndoTherapy accessories, and/or ultrasonic probes to guide the EndoTherapy accessories and/or the ultrasonic probes to the target area within the tracheobronchial tree and collect tissue, specimens, or cells bronchoscopically. This kit and its components are intended for adult patients only.

Single Use Guide Sheath SG-400C

The single use guide sheath has been designed to be used with Olympus bronchoscopes, EndoTherapy accessories, and/or ultrasonic probes to guide the EndoTherapy accessories and/or the ultrasonic probes to the target area within the tracheobronchial tree.

Single Use Biopsy Forceps FB-433D

The biopsy forceps has been designed specifically to collect tissue endoscopically for examination in conjunction with a flexible bronchoscope within the tracheobronchial tree.

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 the bronchoscope within the tracheobronchial tree.

Single Use Guiding Device CC-220DR

This instrument has been designed to be used with an Olympus endoscope and guide sheath to guide the guide sheath to the respiratory organs and to collect specimens within the respiratory organs. This device is intended for adult patients only.

6. Comparison of Technological Characteristics

In comparison to their corresponding predicate devices, components of the subject device Single Use Guide Sheath Kit K-401/K-402 and the Single Use Guiding Device CC-220DR have similar technological characteristics as their predicate devices except for the following differences.

Singe Use Guide Sheath Kit K-401/K-402

<Single Use Guide Sheath SG-400C>

- Dimension of diameter and length
- Patient contact materials
- Compatible bronchoscope and accessory
- Sterilization method

<Single Use Biopsy Forceps FB-433D>

Similar as predicate device, except that this component is intended to be compatible to use with the Single Use Guide Sheath SG-400C and compatible bronchoscope together. As the component in the Singe Use Guide Sheath Kit K-401/K-402, the shelf-life of the Single Use Biopsy Forceps FB-403D is claimed to be one-year.

<Single Use Cytology Brush BC-205D>

Similar as predicate device, except that this component is intended to be compatible to use with the Single Use Guide Sheath SG-400C and compatible bronchoscope together. As the component in the Singe Use Guide Sheath Kit K-401, the shelf-life of the Single Use Cytology Brush BC-205D is claimed to be one-year.

Single Use Guiding Device CC-220DR

- Sterilized status and package
- Compatible device
- Device dimension
- Material of handle

The differences above have been validated and it is demonstrated that these technological

features do not raise no new safety issues and are substantially equivalent to the predicate device.

The following standards have been applied to the Single Use Guide Sheath Kit and the Single Use Guiding Device.

Table 2 The list of applicable FDA recognized standards

Standard No.	Standard Title
ISO11135 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
ISO 10993-7 Second edition 2008-10-15	Biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals
ISO 11607-1 First edition 2006-04-15	Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2 First edition 2006-04-15	Packaging for terminally sterilized medical devices - part 2: validation requirements for forming, sealing and assembly processes
ASTM F1980-16	Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices
ISO 10993-1 Fourth edition 2009-10-15	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - part 5: 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 10993-11 Third edition 2017-09	Biological evaluation of medical devices - part 11: tests for systemic toxicity
ISO 14971 Second edition 2007-03-01	Medical devices - application of risk management to medical devices
ASTM F756	Standard Practice for Assessment of Hemolytic Properties of Materials

Standard No.	Standard Title
ISO 10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
USP General Chapter <151>	Pyrogen Test
USP 42, NF 37, General Chapters <85>	Bacterial Endotoxins Test
USP 42, NF 37, General Chapters <161>	Medical Devices-Bacterial Endotoxin and Pyrogen Tests

7. Performance Data

The following performance data are provided in support of the substantial equivalence determination.

Sterilization/shelf-life testing for the Single Use Guide Sheath Kit and the Single Use Guiding Device 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". Prior to the shelf-life testing, simulated distribution tests as well as accelerated aging test were carried out on the test samples of subject device in final finished form.

The real-time aging test for one-year (Single Use Guide Sheath Kit) and three-years (Single Use Guiding Device CC-220DR) to demonstrate the claimed stability and support the results of the accelerated aging test for the subject devices.

Biocompatibility testing for Single Use Guide Sheath Kit and the Single Use Guiding Device 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".

Performance testing was carried out to demonstrate the safety and the effectiveness of the subject devices.

- Radiographic Testing
- Catheter Joint/Tensile Testing
- Dimensional Testing
- Simulated Use Testing
- Trackability Testing (insertion & withdrawal)

Risk analysis for the Single Use Guide Sheath Kit and the Single Use Guiding Device 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.

8. Conclusion

In comparison to the predicate devices, the Single Use Guide Sheath Kit and the Single Use Guiding Device raise no new safety issues and are substantially equivalent to the predicate device.