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

Re: K212667
Trade/Device Name: Single Use Guide Sheath Kit-401, K-402
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ, BTG
Dated: August 20, 2021
Received: August 23, 2021

Dear Teffany Hutto:

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,

Brandon Blakely, PhD
Acting Assistant Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

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

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.

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."

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

DATE: August 20, 2021

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:

Teffany Hutto
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 512-508-6550
FAX: 484-896-7128
Email: teffany.hutto@olympus.com

■ 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

■ 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**

Device name	510(k) Submitter	510(k) No.
Single Use Guide Sheath Kit K-401/K-402	OLYMPUS MEDICAL SYSTEMS CORP.	K192164

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

<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.

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.

- 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.

6. Comparison of Technological Characteristics

In comparison to the predicate device, the subject device Single Use Guide Sheath Kit K-401/K-402 have the same technological characteristics as the predicate device except the outer diameter of the SG-400C guide sheath.

The specifications other than outer diameter of the guide sheath are identical to those of the predicate device.

Table 2 Comparison of SG-400C Maximum insertion portion diameter

SG-400C (Subject Device)	SG-400C (Predicate Device : K192164)
φ1.91mm	φ1.95mm

The difference above has been validated and it is demonstrated that this technological

feature does 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.

Table 3 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 Second edition 2019-02	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 Third edition 2019-12	Medical devices - application of risk management to medical devices
ASTM F756	Standard Practice for Assessment of Hemolytic Properties of Materials
ISO 10993-4 Third edition 2017-04	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.

No modification was applied to sterilization/shelf-life. Therefore, Sterilization/shelf-life testing was not performed.

No modification was made to the patient contacting materials of the subject device. The modified guide sheath can be covered by the existing biocompatibility testing data provided in the predicate device 510(k).

Performance testing was carried out to demonstrate the safety and the effectiveness of the subject devices. Since the FB-433D and BC-205D have no specification changes, these tests were performed for SG-400C only.

- 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 14971:2019. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

Clinical testing was not applicable and not performed.

8. Conclusion

In comparison to the predicate devices, the Single Use Guide Sheath Kit raises no new safety issues and is substantially equivalent to the predicate device.