September 26, 2022

Olympus Medical Systems Corp.
% Brenda Geary
Manager, Regulatory Affairs
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K221631
Trade/Device Name: Tracheal Intubation Fiberscope OLYMPUS LF-P, VISERA Tracheal Intubation Videoscope OLYMPUS LF Type V
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: August 19, 2022
Received: August 19, 2022

Dear Brenda Geary:

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 Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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)*
K221631

Device Name
Tracheal Intubation Fiberscope OLYMPUS LF-P
VISERA Tracheal Intubation Videoscope OLYMPUS LF Type V

Indications for Use *(Describe)*
The TRACHEAL INTUBATION FIBERSCOPE OLYMPUS LF-P has been designed to be used with an Olympus video system center, documentation equipment, display monitor and other ancillary equipment for airway management, which includes endoscopic observation to access airway anatomy, endotracheal/endobronchial intubation and management.

The VISERA TRACHEAL INTUBATION VIDEOSCOPE OLYMPUS LF TYPE V has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, suction pump, and other ancillary equipment for airway management which includes endoscopic observation to access airway anatomy, endotracheal/endobronchial intubation and management.

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.

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Date Prepared: June 3, 2022

510(k) Summary

A. SPONSOR INFORMATION

510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi,
Tokyo, Japan 192-8507

Official Correspondent: Brenda Geary
Olympus Corporation of the Americas
800 West Park Drive
Westborough, MA 01581
Cell: (928) 707-2852
Email: brenda.geary@olympus.com

Official Correspondent: Brenda Geary

B. DEVICE IDENTIFICATION

■ **Device Name(s):**	TRACHEAL INTUBATION FIBERSCOPE OLYMPUS LF-P VISERA TRACHEAL INTUBATION VIDEOSCOPE OLYMPUS LF TYPE V
■ **Model Name(s):**	OLYMPUS LF-P, OLYMPUS LF-V
■ **Common Name:**	Tracheal Intubation Videoscope
■ **Regulation Number:**	874.4680
■ **Regulation Name:**	Bronchoscope (flexible or rigid) and accessories
■ **Regulatory Class:**	II
■ **Product Code:**	EOQ: Bronchoscope (Flexible or Rigid)
■ **Classification Panel:**	Division of Dental and ENT Devices (DHT1B)

C. PREDICATE DEVICES

■ **Predicate device for LF-P**

Device Name	510(k) Submitter	510(k) No.
PREDICATE		
OLYMPUS LF-TP AND LF-DP Tracheal Intubation Fiberscopes, Accessories and Ancillary Equipment	Olympus Optical Co., Ltd.	K981543

■ **Predicate devices for LF-V**

Device Name	510(k) Submitter	510(k) No.
PREDICATE		
OLYMPUS LF-TP AND LF-DP Tracheal Intubation Fiberscopes, Accessories and Ancillary Equipment	Olympus Optical Co., Ltd.	K981543
REFERENCE PREDICATE		
Tracheal Intubation Fibervideoscope LF-Y0004 and LF-Y0005	Olympus Medical Systems Corp.	K082720

D. DEVICE DESCRIPTION

LF-P Device Description

The TRACHEAL INTUBATION FIBERSCOPE OLYMPUS LF-P has been designed to be used with an Olympus video system center, documentation equipment, display monitor and other ancillary equipment for airway management, which includes endoscopic observation to access airway anatomy, endotracheal/endobronchial intubation and management.

LF-V Device Description

The VISERA TRACHEAL INTUBATION VIDEOSCOPE OLYMPUS LF TYPE V has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, suction pump, and other ancillary equipment for airway management which includes endoscopic observation to access airway anatomy, endotracheal/endobronchial intubation and management.

E. INDICATIONS FOR USE

LF-P Indications for Use

The TRACHEAL INTUBATION FIBERSCOPE OLYMPUS LF-P has been designed to be used with an Olympus video system center, documentation equipment, display monitor and other ancillary equipment for airway management, which includes endoscopic observation to access airway anatomy, endotracheal/endobronchial intubation and management.

LF-V Indications for Use

The VISERA TRACHEAL INTUBATION VIDEOSCOPE OLYMPUS LF TYPE V has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, suction pump, and other ancillary equipment for airway management which includes endoscopic observation to access airway anatomy, endotracheal/endobronchial intubation and management.

F. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

LF-P Tracheal Intubation Fiberscope

	SUBJECT DEVICE: *LF-P Tracheal Intubation Fiberscope*	**PRIMARY PREDICATE:** *LF-DP Tracheal Intubation Fiberscopes (K981543)*
Manufacturer	**Olympus Medical**	**SAME**
Classification & Regulation Number	Class II 21 CFR §874.4680	**SAME**
Product Code	**EOQ** - Bronchoscope (Flexible or Rigid)	**SAME**
Intended Use	The TRACHEAL INTUBATION FIBERSCOPE OLYMPUS LF-P has been designed to be used with an Olympus video system center, documentation equipment, display monitor and other ancillary equipment for airway management, which includes endoscopic observation to access airway anatomy, endotracheal/endobronchial intubation and management.	These instruments have been designed to be used with a Suction Pump and other ancillary equipment for airway management, which includes observation to access airway anatomy, endotracheal/endobronchial intubation and management. Do not use these instruments for any purpose other than their intended use.
Field of View	75°	90°
Direction of View	0° (Forward viewing)	**SAME**
Depth of Field	2-50mm	3-50mm
Optimum Working Distance	7.0mm	6.0mm
Insertion Tube Diameter	Distal end size: ø 1.8mm Flexible tube outer Diameter: ø 2.2mm	Distal end size: ø 3.1mm Flexible tube outer Diameter: ø 3.1mm
Insertion section	600mm	**SAME**

	SUBJECT DEVICE: *LF-P Tracheal Intubation Fiberscope*	PRIMARY PREDICATE: *LF-DP Tracheal Intubation Fiberscopes (K981543)*
Working Length		
Angulation Range	Up 120° / Down 120°	**SAME**
Light Guide (LG) Cable Configuration	Not detachable	Detachable

LF-V Tracheal Intubation Videoscope

	SUBJECT DEVICE: *LF-V Tracheal Intubation Videoscope*	PRIMARY PREDICATE: *LF-DP Tracheal Intubation Fiberscopes (K981543)*	REFERENCE PREDICATE: *LF-Y0004 Tracheal Intubation Fibervideoscope (K082720)*
Manufacturer	**Olympus Medical**	**Olympus Medical**	**Olympus Medical**
Classification & Regulation Number	Class II 21 CFR §874.4680	**SAME**	**SAME**
Product Code	**EOQ** - Bronchoscope (Flexible or Rigid)	**SAME**	**SAME**
Intended Use	The VISERA TRACHEAL INTUBATION VIDEOSCOPE OLYMPUS LF TYPE V has been designed to be used with a video system center, light source, documentation equipment, display monitor, suction pump, and other ancillary equipment for airway management which includes endoscopic observation to access airway anatomy, endotracheal/endobronchial intubation and management.	These instruments have been designed to be used with a Suction Pump and other ancillary equipment for airway management, which includes observation to access airway anatomy, endotracheal/endobronchial intubation and management. Do not use these instruments for any purpose other than their intended use.	These instruments have been designed to be used with a Suction Pump and EndoTherapy accessories and other ancillary equipment for airway management, which includes endoscopic treatment, diagnosis, and observation to access airway anatomy, endotracheal/endobronchial intubation and management.
Field of View	120°	90°	90°
Direction of View	0° (Forward viewing)	**SAME**	**SAME**
Depth of Field	3-50mm	**SAME**	4-50 mm
Optimum Working Distance	9.0mm	6.0mm	9.5mm
Insertion Tube Diameter	Distal end size: ø 3.8mm Flexible tube outer Diameter: ø 4.1mm	Distal end size: ø 3.1mm Flexible tube outer Diameter: ø 3.1mm	Distal end size: ø 3.9mm Flexible tube outer Diameter: ø 4.1mm
Insertion section Working Length	600mm	**SAME**	**SAME**

	SUBJECT DEVICE: *LF-V Tracheal Intubation Videoscope*	PRIMARY PREDICATE: *LF-DP Tracheal Intubation Fiberscopes (K981543)*	REFERENCE PREDICATE: *LF-Y0004 Tracheal Intubation Fibervideoscope (K082720)*
Angulation Range	Up 120° / Down 120°	**SAME**	**SAME**
Light Guide (LG) Cable Configuration	Not detachable	Detachable	None

G. PERFORMANCE DATA

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

- **General**
  - ISO 14971 (Medical devices — Application of risk management to medical devices)
- **Non-Clinical Bench Testing**

  Electrical Testing:
  - IEC 60601-1 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)
  - IEC 60601-1-2 (Medical electrical equipment - Part 1-2: Collateral Standard: Electromagnetic disturbances - Requirements and tests)
  - IEC 60601-2-18 (Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment)
  - IEC 62471 (Photobiological safety of lamps and lamp systems)

  Performance Testing:
  - ISO 8600 (Endoscopes - Medical endoscopes and endotherapy devices, Part 1: General requirements)
  - Composite durability
  - Color performance
  - Image intensity uniformity (IIU)
  - Field of View and Direction of View
  - Resolution

  Reprocessing:
  - FDA Guidance: *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*

- **Biocompatibility**
  - ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process)
  - ISO 10993-5 (Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity)
  - ISO 10993-10 (Biological evaluation of medical devices - Part 10: Tests for skin

sensitization)

- **Clinical Performance Data**

  Clinical and animal testing were not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish the substantial equivalence of the modifications.

H. CONCLUSION

In summary the LF-P and LF-V are substantially equivalent to the predicate devices and present no new questions of safety or effectiveness.