January 26, 2021

Olympus Medical Systems Corp.
% Sheri Musgnung
Regulatory Affairs Manager
Olympus Corporation of the America
3500 Corporate Parkway
PO Box 610
Center Valley, Pennsylvania 18034-0610

Re: K201300
Trade/Device Name: Airway Mobilescope Olympus MAF-DM2, Airway Mobilescope Olympus MAF-GM2, Airway Mobilescope Olympus MAF-TM2
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: December 28, 2020
Received: December 29, 2020

Dear Sheri Musgnung:

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 Malvina B. Eydelman, M.D.
Director
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)*

K201300

Device Name
AIRWAY MOBILESCOPE OLYMPUS MAF-DM2, AIRWAY MOBILESCOPE OLYMPUS MAF-GM2,
AIRWAY MOBILESCOPE OLYMPUS MAF-TM2

Indications for Use *(Describe)*

<AIRWAY MOBILESCOPE OLYMPUS MAF-DM2 and AIRWAY MOBILESCOPE OLYMPUS MAF-GM2>
This instrument has been designed to be used with a Suction Pump and other ancillary equipment for airway management, which includes diagnosis and observation to access airway anatomy, endotracheal/endobronchial intubation and management.

<AIRWAY MOBILESCOPE OLYMPUS MAF-TM2>
This instrument has 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.

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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January 26, 2021
K201300

510(k) Summary

1. GENERAL INFORMATION

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

■ Contact Person: Sheri L. Musgnung
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-3147
Fax: 484-896-7128
Email: sheri.musgnung@olympus.com

■ Manufacturing site: Aizu Olympus Co., Ltd.,
500 Muranishi, Niidera, Monden-machi, Aizuwakamatsu-shi,
Fukushima 965-8520, Japan

2. DEVICE IDENTIFICATION

■ Device Name: AIRWAY MOBILESCOPE

■ Model Name: OLYMPUS MAF-DM2
OLYMPUS MAF-GM2
OLYMPUS MAF-TM2

■ Common Name: AIRWAY MOBILESCOPE

■ Regulation Number: 874.4680

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

■ Regulatory Class: II

■ Product Code: EOQ (Bronchoscope (Flexible or rigid))

■ Classification Panel: Ear, Nose and Throat

3. PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
TRACHEAL INTUBATION FIBERVIDEOSCOPE LF-Y0004 and LF-Y0005	OLYMPUS MEDICAL SYSTEMS CORP.	K082720

■ **Reference device**

As for the AIRWAY MOBILESCOPE OLYMPUS MAF-DM2, a reference device is being utilized to support the substantial equivalence discussion regarding the image capture system.

Device name	510(k) Submitter	510(k) No.
OLYMPUS LF-TP AND LF-DP TRACHEAL INTUBATION FIBERSCOPES, ACCESSORIES AND ANCILLARY EQUIPMENT	Olympus Optical Co., Ltd.	K981543

4. DEVICE DESCRIPTION

■ **General Description of the subject device**

The AIRWAY MOBILESCOPE OLYMPUS MAF-DM2/GM2/TM2 are all in one mobile endoscopes that enables efficient airway management. These endoscopes comprises a 3.5" monitor, LED light source, battery and recording features in a handy single unit, which enable observation without peripherals or cables, allowing them to be used in Intensive Care Unit (ICU), Operating Room (OR) and emergency procedures and so on.

The following items are components and accessories to be marketed with the AIRWAY MOBILESCOPE OLYMPUS MAF-DM2/GM2/TM2.

- MH-364 Cap for MAF-DM2/GM2
- MAJ-1077 Suction Cleaning Adapter for MAF-DM2/GM2
- MAJ-222 Suction Cleaning Adapter for MAF-TM2

■ **Principle of Operation**

Basic principle

The subject devices employ the following principles to obtain observation images of objective part:

Light provided from LED in the control section of the endoscope is transmitted to the distal end of insertion section through light guide fiber bundles in order to illuminate the objective part. The optical image obtained in the distal end is transmitted through the image guide fiber bundles to a Complimentary metal-oxide semiconductor (CMOS) image sensor/processor built in the camera unit which is installed on the top of the control section. The CMOS image sensor/processor converts the optical image into electronic/video signal. The endoscopic image is displayed on the LCD monitor which is provided in the camera section.

Technological characteristics

The technological characteristics of subject devices are basically identical to the predicate devices and the differences of them are described in Section 12.
The key characteristics of the subject devices are described below.

- Incorporate a 3.5-inch monitor to enable observation and control operations in a single view. The monitor is capable of adjustment range from 0 to 90°, which allows physician to tilt the screen to a suitable angle for viewing.
- Both still images and movies can be recorded on a SD card for easy referencing and management. Images can be transferred easily to a PC for additional processing.
- Instead of mechanical shutter, exposure is adjusted appropriately by switching the LED off in synchronization with shutter signals from the camera section when still image is taken.
- Chemical immersion is available under the condition of loading SD card and battery.

5. INDICATIONS FOR USE

AIRWAY MOBILESCOPE OLYMPUS MAF-DM2 and AIRWAY MOBILESCOPE OLYMPUS MAF-GM2

This instrument has been designed to be used with a Suction Pump and other ancillary equipment for airway management, which includes diagnosis and observation to access airway anatomy, endotracheal/endobronchial intubation and management.

AIRWAY MOBILESCOPE OLYMPUS MAF-TM2

This instrument has 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.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The AIRWAY MOBILESCOPE OLYMPUS MAF-DM2/GM2/TM2 has the same technological characteristics and design as the predicate device except for the following new features:

- 3.1 mm distal end diameter of MAF-DM2
- Changes on optical system parameters
- Design change of camera section

All other technological characteristics of both the subject and predicate devices are identical. For details of the comparison, see Table.5.1, 5.2 and 5.3. Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

Table 5.1 Comparison between MAF-TM2 and LF-Y0005

Item	Subject Device	Predicate Device (PD)
	MAF-TM2	LF-Y0005
General Information		
510(k) Number	K201300	K082720
Indications for Use	This instrument has 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.	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.
Regulation Number	874.4680	874.4680
Regulation Name	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories
Regulatory Class	II	II

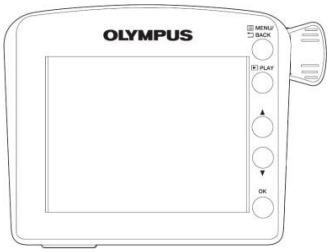
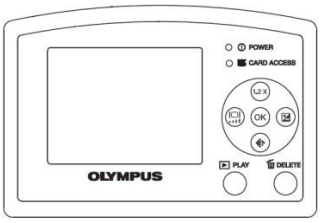
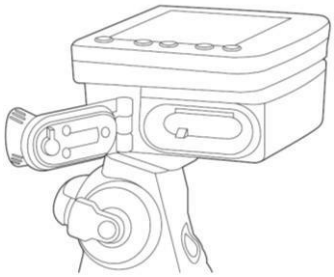
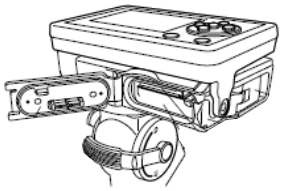
Specification			
Insertion section	Outer Diameter of Distal End	φ5.1mm	φ5.1mm
	Outer Diameter of Insertion Tube	φ5.2mm	φ5.2mm
	Angulation UP/DOWN	180°/130°	180°/130°
	Inner Diameter of Instrument Channel	φ2.6mm	φ2.6mm
	Working Length	600 mm	600 mm
Image capture system	Field of View	90°	90°
	Depth of Field	3-50 mm	3-50 mm
	Direction of View	0° (Forward viewing)	0° (Forward viewing)
	Image Sensor	CMOS	CCD
Camera Section	Video processor	Built in the camera section	Built in the camera section
	Monitor	LCD of the camera section	LCD of the camera section
	LCD	3.5"TFT	2.5"TFT
	Operation		
	Battery/card cover		

Table 5.2 Comparison between MAF-GM2 and LF-Y0004

Item		Subject Device	Predicate Device (PD)
		MAF-GM2	LF-Y0004
General Information			
510(k) Number		K201300	K082720
Indications for Use		This instrument has been designed to be used with a Suction Pump and other ancillary equipment for airway management, which includes diagnosis and observation to access airway anatomy, endotracheal/endobronchial intubation and management.	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.
Regulation Number		874.4680	874.4680
Regulation Name		Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories
Regulatory Class		II	II
Specification			
Insertion section	Outer Diameter of Distal End	φ3.9mm	φ3.9mm
	Outer Diameter of Insertion Tube	φ4.1mm	φ4.1mm
	Angulation UP/DOWN	120°/120°	120°/120°
	Inner Diameter of Instrument Channel	φ1.5mm	φ1.5mm
	Working Length	600 mm	600 mm
Image capture system	Field of View	90°	90°
	Depth of Field	4-50 mm	4-50 mm
	Direction of View	0° (Forward viewing)	0° (Forward viewing)
	Image Sensor	CMOS	CCD

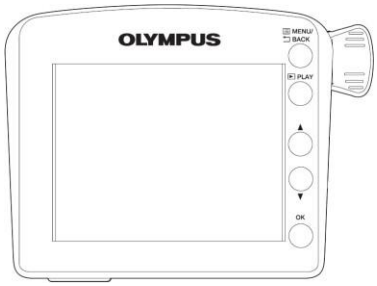
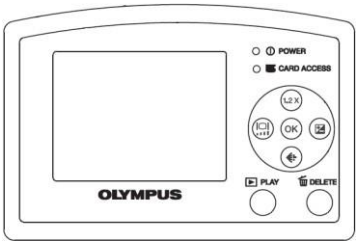
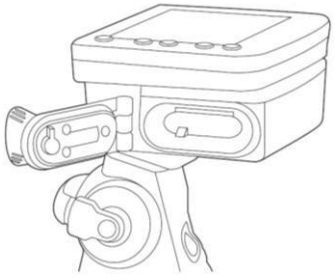
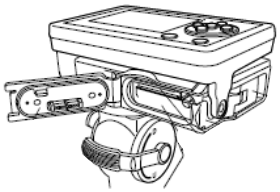
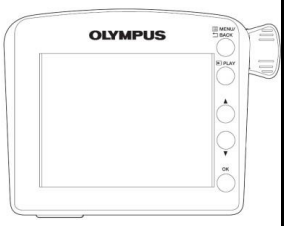
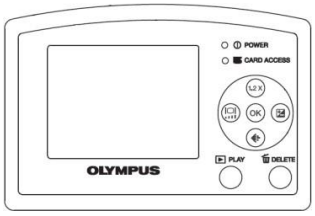
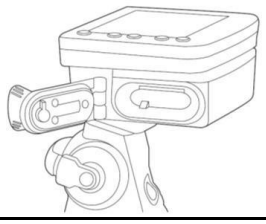
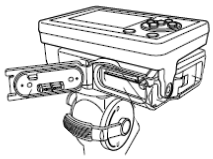
Camera section	Video processor	Built in the camera section	Built in the camera section
	Monitor	LCD of the camera section	LCD of the camera section
	LCD	3.5"TFT	2.5"TFT
	Operation		
	Battery/card cover		

Table 5.3 Comparison between MAF-DM2 and LF-Y0004(PD)/LF-DP(RD)

Item			Subject Device	Predicate Device (PD)	Reference Device(RD)
			MAF-DM2	LF-Y0004	LF-DP
General Information					
510(k) Number			K201300	K082720	K981543
Indications for Use			This instrument has been designed to be used with a Suction Pump and other ancillary equipment for airway management, which includes diagnosis and observation to access airway anatomy, endotracheal/ endobronchial intubation and management.	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.	Olympus LF-TP and F-DP Tracheal Intubation Fiberscope, accessories and ancillary equipment are intended for airway management which includes endoscopic observation to assess airway anatomy, endotracheal/ endobronchial intubation, and management.
Regulation Number			874.4680	874.4680	874.4680
Regulation Name			Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories
Regulatory Class			II	II	II
Specification					
Insertion section	Outer Diameter of Distal End		φ3.1mm	φ3.9mm	φ3.1mm
	Outer Diameter of Insertion Tube		φ3.1mm	φ4.1mm	φ3.1mm

	Angulation UP/DOWN	120°/120°	120°/120°	120°/120°
	Inner Diameter of Instrument Channel	φ1.2mm	φ1.5mm	φ1.2mm
	Working Length	600 mm	600 mm	600 mm
Image capture system	Field of View	90°	90°	90°
	Depth of Field	2-50 mm	4-50 mm	3-50 mm
	Direction of View	0° (Forward viewing)	0° (Forward viewing)	0° (Forward viewing)
	Image Sensor	CMOS	CCD	
Camera section	Video processor	Built in the camera section	Built in the camera section	
	Monitor	LCD of the camera section	LCD of the camera section	
	LCD	3.5"TFT	2.5"TFT	
	Operation			
	Battery/card cover			

7. PERFORMANCE DATA

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

1) Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing for the AIRWAY MOBILESCOPE MAF-DM2/GM2/TM2 were conducted and documentation was provided as recommended by Guidance for Industry and Food and Drug Administration Staff, "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling".

2) Biocompatibility testing

Biocompatibility testing for the AIRWAY MOBILESCOPE MAF-DM2/GM2/TM2 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". The biocompatibility testing included the following tests:

- Cytotoxicity Study Using the Colony Assay
- Intracutaneous Study in Rabbits
- Guinea Pig Maximization Sensitization Test

3) Software verification and validation testing

Software verification and validation testing for the AIRWAY MOBILESCOPES, MAF-DM2/MAF-GM2/ MAF-TM2 were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

4) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the AIRWAY MOBILESCOPES, MAF-DM2/ MAF-GM2/ MAF-TM2. The system complies with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2:2014 standards for EMC.

5) Performance testing - Bench

Bench testing for the AIRWAY MOBILESCOPES, MAF-DM2/ MAF-GM2/ MAF-TM2 as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

- Mechanical durability test
- Thermal safety test
- Depth of field test
- Direction of view test
- Image performance - resolution test
- Signal to noise ratio test
- Dynamic range test
- Photobiological safety test
- Color performance test
- Image intensity uniformity test

6) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

7) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

8) Risk management

Risk management for the AIRWAY MOBILESCOPES, MAF-DM2/ MAF-GM2/ MAF-TM2 was performed in accordance with ISO 14971:2007 and human factors validation was conducted in accordance with the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices". The design verification tests and their acceptance criteria were identified and performed as a result of this risk management.

8. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the AIRWAY MOBILESCOPES, MAF-DM2/ MAF-GM2/ MAF-TM2 raise no new issue of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, effectiveness, and performance.