December 28, 2022

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

Re: K221660
Trade/Device Name: Rhino-Laryngofiberscope Olympus ENF Type XP
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: November 21, 2022
Received: November 21, 2022

Dear Steven Keenan:

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,

Joyce C. Lin -S

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)*
K221660

Device Name
RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP

Indications for Use *(Describe)*
RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP is intended to be used with an Olympus video system center, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis. RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP is indicated for use within the nasal and nasopharyngeal lumen.

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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K221660 - 510(k) Summary

For

RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP

General Information

Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Phone: (+81) 42-642-2694 Fax: (+81) 42-642-2307 Establishment Registration Number: 8010047
Manufacturer:	Aizu Olympus Co., Ltd., 500 Muranishi, Niidera, Monden-machi, Aizuwakamatsu-shi, Fukushima 965-8520, Japan Phone: (+81) 242-28-2111 Fax: (+81) 81-242-26-4234 Establishment Registration Number: 9610595
510(k) Submitter:	Olympus Corporation of the Americas 800 West Park Drive Westborough, MA 01518 USA
Establishment Registration Number:	2429304
Contact Person:	Steven Keenan Program Manager Mobile: (508)-523-5004 Email: Steven.Keenan@olymus.com
Date Prepared:	June 3, 2022

Device Description

Model No.	Device/Trade Name	Product Classification
ENF-XP	RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP	EOB (874.4760)

Classification Name: Nasopharyngoscope (flexible or rigid) and accessories
Generic/Common Name: Rhino-Laryngo Fiberscope
Regulation Number: 874.4760
Regulatory Class: Class II
Product Codes: EOB
Review Panel: Ear Nose & Throat

Predicate Device

Predicate Device	510(k) No.
RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2	K181240

Product Description

RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP is intended to be used with an Olympus video system center, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis. RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP is indicated for use within the nasal and nasopharyngeal lumen.

Comparison of Technological Characteristics

Table 5-1 compares RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP to the predicate device with respect to intended use, technological characteristics, and principle of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 5-1: Comparison of the technological characteristics of ENF-XP to predicate device

Feature/ Technological Characteristics	Subject Device ENF-XP	Predicate Device ENF-GP2	Comparison
Regulatory			
Device Name	RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP	Rhino-Laryngo Fiberscope ENF-GP2	Different model names.
Regulatory Decision	This submission	K181240	N/A

Feature/ Technological Characteristics	Subject Device ENF-XP	Predicate Device ENF-GP2	Comparison
Product Code	EOB	EOB	Same as predicate.
Regulation Number	874.4760	874.4760	Same as predicate.
Regulation Name	Nasopharyngoscope (flexible or rigid) and accessories	Nasopharyngoscope (flexible or rigid) and accessories	Same as predicate.
Intended Use	RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP is intended to be used with an Olympus video system center, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis. RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP is indicated for use within the nasal and nasopharyngeal lumen.	This instrument is intended to be used with an Olympus light source, documentation equipment, display monitor and other ancillary equipment for endoscopic diagnosis. This instrument is indicated for use within the nasal and nasopharyngeal lumen.	Similar to predicate. Device name and model number are now included in the Indications for Use statement. The intended use is identical to predicate.

Feature/ Technological Characteristics	Subject Device ENF-XP	Predicate Device ENF-GP2	Comparison
Mode of Action	When observing nasal or nasopharyngeal lumen, the light emitted from light source enters into the fiberscope via apparatus on connector section and is eventually transmitted and released from examination light outlet in the distal end to supply light by optical fiber bundles. Subsequently the illuminated image reflected into objective lens is sent to the eyepiece section by image fiber bundles. The observer can observe the image directly in the eyepiece section or alternatively, the image can be observed on a monitor generated by a video processor and a camera head attached on the eyepiece.	When observing nasal or nasopharyngeal lumen, the light emitted from light source enters into the fiberscope via apparatus on connector section and is eventually transmitted and released from examination light outlet in the distal end to supply light by optical fiber bundles. Subsequently the illuminated image reflected into objective lens is sent to the eyepiece section by image fiber bundles. The observer can observe the image directly in the eyepiece section or alternatively, the image can be observed on a monitor generated by a video processor and a camera head attached on the eyepiece.	Same as predicate.
Optical System Parameters			
Field of View	75°	85°	Although the field of view is different from PD, the area within the view can be adjusted by the advance or retreat of the endoscope. Therefore, the difference in FOV does not affect the safety and effectiveness of the subject device.
Direction of View	0° (Forward viewing)	0° (Forward viewing)	Same as predicate.

Feature/ Technological Characteristics	Subject Device ENF-XP	Predicate Device ENF-GP2	Comparison
Depth of Field	2.5-50 mm	5-50 mm	The increased range of depth of field covers the PD's depth of field. In addition, although the subject device is compatible with various processors, light sources, and camera heads, this specification is not affected by the variation of the systems.
Bending Section			
Angulation range	Up 130° / Down 130°	Up 130° / Down 130°	Same as predicate.
Insertion section			
Insertion Tube Diameter – Distal End	1.8 mm	3.1 mm	The difference in tube diameter of the distal end for the subject device does not alter or change the indications for use or result in a new intended use.
Insertion Tube Diameter – Flexible Outer Diameter	2.2mm	3.5mm	The difference in flexible outer diameter of the insertion tube for the subject device does not alter or change the indications for use or result in a new intended use.
Insertion Section Working Length	300 mm	300 mm	Same as predicate.
Connection to Light Source			
Configuration	Light Guide (LG) cable is not detachable	LG cable is detachable	Cable configuration does not directly affect the safety and effectiveness of the subject device.
Venting Connector			
Venting Connector Position	On LG connector	On control body	Venting connector position does not directly affect the safety and effectiveness of the subject device.
Sterilization			
EO	Available	Available	Same as predicate.
Other			
Suction Function	Not provided	Not provided	Same as predicate.
Total Length	530 mm	550 mm	Due to the difference in the shape of the control section, the subject device has a 20mm shorter total length compared with the predicate device. This difference does not alter or change the indications for use or result in a new intended use.
Compatible processor/Light Source/Monitor			

Feature/ Technological Characteristics	Subject Device ENF-XP	Predicate Device ENF-GP2	Comparison
Compatible Processor	OTV-S200/S300 (with light source function)	OTV-SC/SC2 OTV-S7V CV-170 OTV-S7Pro OTV-S190	Compatibility of ENF- XP with OTV-S200/S300 was demonstrated with bench performance testing in Section 18 confirm that these additional processors do not raise any new questions of safety or effectiveness.
Compatible Light Source	OTV-S200/S300 (with light source function)	CLV-S190 CLV-S40Pro CLH-SC CLL-V1 CLL-S1 CV-170	Compatibility of ENF- XP with OTV-S200/S300 (with light source function) was demonstrated with bench performance testing in Section 18 confirm that these additional light sources do not raise any new questions of safety or effectiveness.
Compatible Monitor	OEV-262H LMD-X310ST* *This can only be combined with OTV-S300.	OEV-141 OEV-142 OEV-143 OEV-201 OEV-202 OEV-203 OEV-181H OEV-191 OEV-191H OEV-261H	Compatibility of ENF- XP with OEV-262H and LMD-X310ST was demonstrated with bench performance testing in Section 18 confirm that these additional monitors do not raise any new questions of safety or effectiveness.
Compatible Camera Head	CH-S200-XZ-EA CH-S200-XZ-EB	OTV-S7H-1NA-10E/12E OTV-S7H-1N/1NA OTV-S7ProH-HD-10E/12E	Compatibility of ENF- XP with CH-S200-XZ-EA and CH-S200-XZ-EB camera heads was demonstrated with bench performance testing in Section 18 confirm that these additional camera heads do not raise any new questions of safety or effectiveness.

Indications for Use

RHINO-LARYNGOFIBROSCOPE OLYMPUS ENF TYPE XP is intended to be used with an Olympus video system center, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis. RHINO-LARYNGOFIBROSCOPE OLYMPUS ENF TYPE XP is indicated for use within the nasal and nasopharyngeal lumen.

Compliance to Voluntary Standards

The following voluntary standards have been applied to the subject devices respectively:

Standard	
ANSI AAMI ES 60601-1:2005+A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-2-18:2009	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 62471:2006	Photobiological safety of lamps and lamp systems
ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO 10993-17:2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
ISO 11135:2014	Sterilization of health care products – Ethylene Oxide – requirements for development, validation and routine control of a sterilization process for medical devices
ISO 10993-7: 2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)
ISO 14971:2007	Medical Devices – Application of risk management to medical devices
FDA Device Specific Guidance	
Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff	
FDA Guidance Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	
Guidance for the Content of Premarket Submissions for Software contained in Medical Devices	
FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices	

Summary of Performance Testing

The following performance testing was conducted in support of the substantial equivalence determination.

1. Non-Clinical Bench Testing

Item	Contents
Thermal Safety	Thermal safety performance test verified compliance to Protection against excessive temperature and other safety hazards of IEC 60601-2-18:2009-08.
Composite Durability	The durability test against composite stress of mechanical and chemical stress demonstrates the subject device retains its safety and effectiveness against the stresses expected in its use-life.
Color Performance	The color performance of the subject devices is confirmed as substantially equivalent to the predicate devices.
Image Intensity Uniformity	The image intensity uniformity of the subject devices is confirmed as substantially equivalent to the predicate devices.
Resolution	The resolution of the subject device is similar to predicate device and does not raise new issues of safety or effectiveness.
Photobiological Safety	The photobiological safety test verified compliance to IEC 62471:2006-07 and confirms the light emitted from subject devices connected to each light source is low enough not to cause injury to the skin and eye.
Direction of View	The direction of view test verified compliance to ISO 8600-1 and confirms that the subject device is consistent with the design specifications and does not introduce new questions related to safety and effectiveness.
Field of View	The field of view test verified compliance to ISO 8600-1 and confirms that the subject device is consistent with the design specifications and does not introduce new questions related to safety and effectiveness.

2. Animal Test

Animal testing was not applicable and not performed.

3. Biocompatibility Evaluation

Biocompatibility testing was 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". There have been no changes that have impacted the established biocompatibility profile and the Biological Risk associated with this device is acceptable for intended use.

4. Sterilization, Shelf Life, Reprocessing

RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP and its reusable accessories are not sterilized before shipment. Before using the instrument for the first time and after using the endoscopes, the devices are reprocessed according to the instructions given in the subject endoscope's companion Reprocessing Manual. All cleaning, disinfection, and sterilization methods were validated pursuant to the FDA guidance, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff*, issued March 17, 2015. The reprocessing validation was conducted

pursuant to the same FDA guidance document. ENF-XP is validated as safe and effective for reprocessing with the following:

- Manual Cleaning using FlexClean895
- Manual Cleaning using Endozime AW
- Manual Cleaning with pre-soaking using Endozime AW
- Manual Disinfection (2-3.5%glutaraldehyde)
- OER-Pro (K103264)
- OER-Mini (K120357)
- OER-Elite (K201920)
- Sterilization with EO Gas

5. Electrical Safety

Electrical safety testing has been confirmed for the subject devices. RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP was found to be in compliance with the relevant requirements as noted below. Electromagnetic compatibility (EMC) testing was not applicable and not performed.

- IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

6. Software Verification and Validation Testing

RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP does not contain any software and therefore software testing was not performed.

7. Risk Analysis

Risk management has been performed in accordance with ISO 14971:2007. In the risk management process, Olympus determined that additional human factors validation testing was not required for the subject device in accordance with the FDA Guidance, "*Applying Human Factors and Usability Engineering to Medical Devices*" since the risk analysis made to the currently marketed device did not identify any unacceptable use-related risks. Refer to the risk management table for the RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP. To date, with respect to perceivable conditions in which the device would be subjected to a worst-case environment for human error scenario, Olympus believes that the outcomes of these risks are considered acceptable within the context of ISO 14971:2007 and that all potential risks have been mitigated to the lowest form.

8. Clinical Testing

Clinical testing was not applicable and not performed.

Substantial Equivalence

RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP is substantially equivalent to the legally marketed predicate device, ENF-GP2 (K181240). Olympus claims substantial equivalence to the predicate devices based on evaluation of the on similarities in indications for use, design, materials, technological characteristics, and operational characteristics. Differences are summarized in **Table 5-1** above.

Conclusion

In summary, the indications for use and technological characteristics of the RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP device do not raise different questions of safety and effectiveness as compared to the predicate device. The performance testing demonstrate that the subject device is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate device.