October 4, 2018

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

Re: K181240
Trade/Device Name: Rhino-Laryngo Fiberscope Olympus ENF-GP2
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: August 31, 2018
Received: September 4, 2018

Dear Sheri L. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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)*
K181240

Device Name
RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2

Indications for Use *(Describe)*
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.

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.

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510(k) SUMMARY
RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2

October 1, 2018

1 General Information

■ Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
Establishment Registration No: 8010047

■ Official Correspondent: Sheri L. Musgnung
Manager, Regulatory Affairs
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

■ Manufacturer: Aizu Olympus Co., Ltd.
500 Muranishi, Niidera, Monden-Machi,
Aizuwakamatsu- Shi, Fukushima, 965-8520, Japan
Establishment Registration No.: 9610595

2 Device Identification

■ Device Trade Name:	RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2
■ Common Name:	RHINO-LARYNGO FIBERSCOPE
■ Regulation Number:	874.4760
■ Regulation Name:	Nasopharyngoscope (flexible or rigid) and accessories
■ Regulatory Class:	II
■ Classification Panel:	Ear Nose and Throat
■ Product Code:	EOB

3 Predicate Device Information

■ Device Name:	XENF-TP Rhino-Laryngofiberscope, its accessories and ancillary equipment
■ Common Name:	Fiber Scope for Rhino-Laryngo
■ Applicant	OLYMPUS MEDICAL SYSTEMS CORP.
■ 510(k) No.	K013591

4 Device Description

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.

ENF-GP2 is mainly consisted of four functional parts:

- eyepiece section that observes endoscopic images
- control section that operates endoscope such as controlling angulation to guide insertion and observation
- connector section that links with light source
- insertion section that goes through and contacts with nasal and nasopharyngeal lumen under light guide.

When observing nasal or nasopharyngeal lumen, the light emitted from light source comes into 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 enlighten image reflexed into objective lens is grasped and sent to eyepiece section by image fiber bundles, and observer can observe the image in eyepiece section or alter the imaging position by means of operations on control section, such as manipulation by UP/DOWN angulation control lever to adjust the bending section. Each section works collectively to perform observation within nasal and nasopharyngeal lumen.

5 Indications for Use

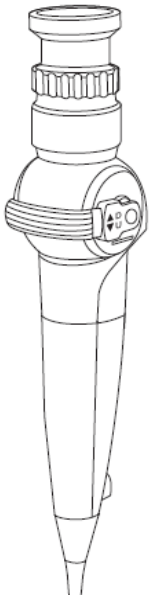
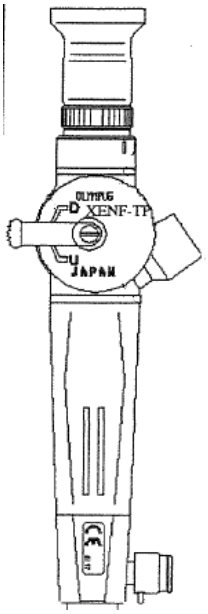
This instrument is intended to be used with an Olympus light source, documentation equipment, display monitor and other ancillary equipment for endoscopic diagnosis. This instrument is indicated for use within the nasal and nasopharyngeal lumen.

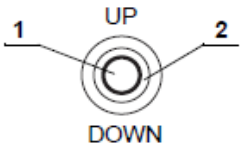
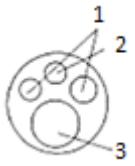
6 Comparison of Technological Characteristics

Compared to the predicate device, the subject device RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2 has similar technological characteristics except for the following differences:

- Changes on optical system parameters
- Configuration modification and material change of eyepiece section and control section
- Dimension and material change on insertion section
- Removal of instrumental channel structure
- Extension of reprocessing methods

Detailed information is provided in the following table.

Features	<Subject Device> RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2	<Predicate Device> XENF-TP Rhino-Laryngofiberscope, its accessories and ancillary equipment, K013591
Indications for use	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.	This instrument has been designed to be used with an Olympus light source or an Olympus miniature light source, documentation equipment, display monitor. Endotherapy accessories and other ancillary equipment for endoscopic diagnosis and treatment within the nasal and nasopharyngeal lumen. Do not use this instrument for any purpose other than its intended use.
Field of view	85°	85°
Direction of view	0°(forward viewing)	0°(forward viewing)
Depth of field	5-50mm	3-50mm
Configuration and material change of eyepiece and control section		

Features	<Subject Device> RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2	<Predicate Device> XENF-TP Rhino-Laryngofiberscope, its accessories and ancillary equipment, K013591
Outer diameter of distal end	φ3.1mm	φ4.8mm
Outer diameter of insertion tube	φ3.5mm	φ5.0mm
Working length of insertion section	300mm	365mm
Angulation angle	130°	130°
Channel for therapy accessories	none	Incorporated
Construction of objective lens and light guide lens	 1. objective lens 2. light guide lens	 1. light guide lenses 2. objective lens 3. instrument channel
Total length	550mm	620mm
Reprocess with OER-Pro	available	unavailable
Sterilization with STERRAD	available	unavailable
Sterilization with V-PRO	available	unavailable

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 RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2 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 RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2 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".

3) Performance testing - Bench

Bench testing for the RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2 as listed below was conducted. Electrical safety test has been performed to verify the compliance to ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012, IEC60601-2-18:2009, thermal safety test has been performed to verify the compliance to "PROTECTION AGAINST EXCESSIVE TEMPARATURES AND OTHER SAFETY HAZARDS" of IEC 60601-2-18:2009-08, durability test has been performed to verify the safety and effectiveness considering the supposed usage and operating environment and optical performance test has been performed to verify the safety and effectiveness from optical perspective.

- Electrical Safety followed by ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012, IEC60601-2-18:2009
- Thermal safety test
- Mechanical durability test
- Optical performance test

4) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

5) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

6) Risk analysis

Risk analysis for the RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2 was

conducted in accordance with established in-house acceptance criteria based on ISO 14971:2007 and the 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 analysis assessment.

8 Conclusion

When compared to the predicate device, the RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2 does not cause any significant changes in intended use and technical characteristics that could affect the safety or effectiveness of the device.