September 19, 2022

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

Re: K221638
Trade/Device Name: Rhino-Laryngo Videoscope Olympus ENF-VH, Rhino-Laryngo Videoscope Olympus ENF-V3
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB, NWB
Dated: August 9, 2022
Received: August 18, 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,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and Ear, Nose and Throat 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)*
TBD

Device Name
RHINO-LARYNGO VIDEOSCOPE, OLYMPUS MODEL: ENF-VH
RHINO-LARYNGO VIDEOSCOPE, OLYMPUS MODEL: ENF-V3

Indications for Use *(Describe)*
RHINO-LARYNGO VIDEOSCOPEs OLYMPUS ENF-V3 and ENF-VH are intended to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis. RHINO-LARYNGO VIDEOSCOPEs OLYMPUS ENF-V3 and ENF-VH is indicated for use within the nasal lumens and airway anatomy (including nasopharynx and trachea).

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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510(k) Summary

RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH, ENF-V3

General Information

Applicant:

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192-8507
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Establishment Registration Number:
3002808148

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Japan
Phone: (+81) 242-28-2111
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Establishment Registration Number: 9610595

510(k) Submitter:

Olympus Corporation of the Americas
800 West Park Drive
Westborough, MA 01581 USA

Establishment Registration Number: 2429304

Contact Person:

Brenda M Geary
Manager, Regulatory Affairs
Mobile: (508) 683-9561
Email: brenda.geary@olympus.com

Date Prepared: 3 June 2022

Device Description

Model No.	Device/Trade Name	Product Classification
ENF-VH	RHINO-LARYNGO VIDEOSCOPE	EOB (874.4760) NWB
ENF-V3		

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

Predicate Devices

Predicate Device	510(k) No.
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH2, ENF-V4	K182102

Product Description

Rhino-Laryngo Videoscopes Olympus ENF-VH, ENF-V3 are intended to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis. Rhino-Laryngo Videoscopes Olympus ENF-VH, ENF-V3 are indicated for use within the nasal lumens and airway anatomy (including nasopharynx and trachea).

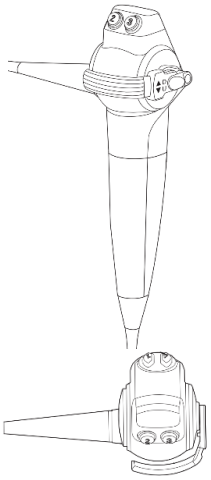
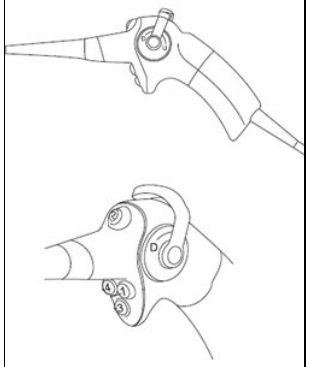
Comparison of Technological Characteristics

Table 5-1 compares ENF-VH 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-VH to predicate device

Feature/Technological Characteristics	Subject Device ENF-VH	Predicate Device ENF-VH2	Comparison
Regulatory			
Device Name (Model)	Rhino-Laryngo Videoscope (ENF-VH)	Rhino-Laryngo Videoscope (ENF-VH2)	Model names differ.
Regulatory Decision	This submission	K182102	N/A
Product Code	EOB, NWB	EOB, NWB	Same as predicate
Regulation Number	874.4760,	874.4760,	Same as predicate
Regulation Name	Nasopharyngoscope (flexible or rigid) and accessories, Endoscope and accessories	Nasopharyngoscope (flexible or rigid) and accessories, Endoscope and accessories	Same as predicate

Feature/Technological Characteristics	Subject Device ENF-VH	Predicate Device ENF-VH2	Comparison
Intended Use	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH is intended to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis. RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH is indicated for use within the nasal lumens and airway anatomy (including nasopharynx and trachea).	This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis. This instrument is indicated for use within the nasal lumens and airway anatomy (including nasopharynx and trachea).	Similar to predicate. Device name and model number are now included in the Indications for Use statement. The actual intended use is identical.
Mode of Action	The endoscope receives the illumination light from the light source by light guide connector connected to the light source device. The illumination light is transferred to the distal end through the optical fiber bundle inside of the endoscope and illuminates the inside of the patient body through the illumination lens at the distal end. The endoscope receives the reflected light from the inner lumen of a patient by objective lens at the distal end.	The endoscope receives the illumination light from the light source by light guide connector connected to the light source device. The illumination light is transferred to the distal end through the optical fiber bundle inside of the endoscope and illuminates the inside of the patient body through the illumination lens at the distal end. The endoscope receives the reflected light from the inner lumen of a patient by objective lens at the distal end.	Same as predicate
Optical System Parameters			
Field of View	110°	110°	Same as predicate
Direction of View	0° forward viewing	0° forward viewing	Same as predicate
Depth of Field (Refer to Attachment 12-B for the definition)	5-50 mm	5-50 mm	Same as predicate
Imaging System			
Type of Chip	Color CCD	Color CCD	Same as predicate
No. of Image Sensor Chip	1	1	Same as predicate
NBI observation	Available	Available	Same as predicate
Control Section			

Feature/Technological Characteristics	Subject Device ENF-VH	Predicate Device ENF-VH2	Comparison
Control Section			The control section of the Rhino-Laryngo Videoscopes (ENF-VH/V3) were designed have the same control mechanism however they are designed to be handled with up-right functionality rather than a pistol and trigger grip. The difference in the ergonomic design does not raise new questions of safety and effectiveness This difference does not alter or change the indications for use or result in a new intended use.
Total Length	510 mm	500 mm	Similar Total length difference is due to change in design of the control section for the subject device. This difference does not alter or change the indications for use or result in a new intended use.
Insertion section			
Insertion Tube Diameter – Distal End	3.9 mm	3.9 mm	Same as predicate
Insertion Tube Diameter – Flexible Outer Tube	3.6 mm	3.6 mm	Same as predicate
Insertion Section Working Length	300 mm	300 mm	Same as predicate
Bending section			
Angulation range	Up 130° / Down 130°	Up 130° / Down 130°	Same as predicate
Connection to Light Source			
Configuration	Light guide (LG) cable is not detachable	Light guide (LG) cable is not detachable	Same as predicate
Venting Connector			
Position	On LG connector	On LG connector	Same as predicate
Sterilization			
EO	Available	Available	Same as predicate
STERRAD NX	Available	Available	Same as predicate
STERRAD 100S	Available	Available	Same as predicate
Compatible Processor/Light Source/Monitor			

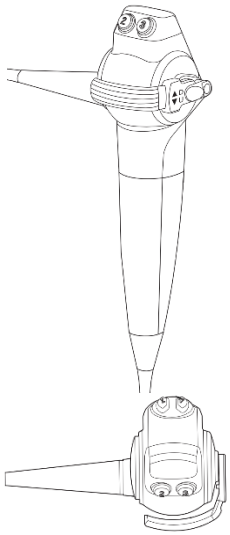
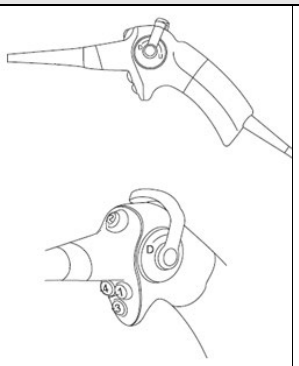
Feature/Technological Characteristics	Subject Device ENF-VH	Predicate Device ENF-VH2	Comparison
Compatible Processor	OTV-S200/S300 OTV-S190 CV-170	OTV-S190 CV-170	For VH- qualified additional processors OTV-S200/S300. Compatibility of ENF-VH with OTV-S200/S300 was demonstrated with bench performance testing in Section 18 confirm that these additional processors do not raise any new questions of safety or effectiveness.
Compatible Light Source	CLV-S190 CLL-S1	CLV-S190 CLL-S1	Same as predicate
Compatible Monitor	OEV262H LMD-X310ST* *This can only be combined with OTV-S300.	OEV262H OEV-261H OEV-191H	For VH- qualified LMD-X310ST. Compatibility of ENF-VH with LMD-XS310ST was demonstrated during electrical safety and electromagnetic compatibility testing described in Section 17 confirm that this monitor does not raise new questions of safety or effectiveness.

Table 5-2 compares subject device ENF-V3 to the predicate device ENF-V4 with respect to intended use, technological characteristics, and principle of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 5-2: Comparison of the technological characteristics of ENF-V3 to predicate device

Feature/ Technological Characteristics	Subject Device ENF-V3	Predicate Device ENF-V4	Comparison
Regulatory			
Device Name (Model)	Rhino-Laryngo Videoscope (ENF-V3)	Rhino-Laryngo Videoscope (ENF-V4)	Model names differ
Regulatory Decision	This submission	K182102	N/A
Product Code	Same as predicate	EOB, NWB	Same as predicate
Regulation Number	Same as predicate	874.4760	Same as predicate
Regulation Name	Same as predicate	Nasopharyngoscope (flexible or rigid) and accessories, Endoscope and accessories.	Same as predicate
Intended Use	RHINO-LARYNGO VIDEOSCOPE	This instrument is intended to be used with	Similar to predicate. Device name and model

Feature/ Technological Characteristics	Subject Device ENF-V3	Predicate Device ENF-V4	Comparison
	OLYMPUS ENF-V3 is intended to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis. RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V3 is indicated for use within the nasal lumens and airway anatomy (including nasopharynx and trachea).	an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis. This instrument is indicated for use within the nasal lumens and airway anatomy (including nasopharynx and trachea).	number are now included in the Indications for Use statement. The actual intended use is identical.
Mode of Action	The endoscope receives the illumination light from the light source by light guide connector connected to the light source device. The illumination light is transferred to the distal end through the optical fiber bundle inside of the endoscope and illuminates the inside of the patient body through the illumination lens at the distal end. The endoscope receives the reflected light from the inner lumen of a patient by objective lens at the distal end.	The endoscope receives the illumination light from the light source by light guide connector connected to the light source device. The illumination light is transferred to the distal end through the optical fiber bundle inside of the endoscope and illuminates the inside of the patient body through the illumination lens at the distal end. The endoscope receives the reflected light from the inner lumen of a patient by objective lens at the distal end.	Same as predicate
Optical System Parameters			
Field of View	90°	90°	Same as predicate
Direction of View	0° Forward Viewing	0° Forward Viewing	Same as predicate
Depth of Field (Refer to Attachment 12-B for the definition)	*3.5-50 mm	*3.5-50 mm	Same as predicate
Imaging System			
Type of Chip	Color CCD	Color CCD	Same as predicate
Number of Image Sensor Chip	1	1	Same as predicate
NBI Observation	Available	Available	Same as predicate

Feature/ Technological Characteristics	Subject Device ENF-V3	Predicate Device ENF-V4	Comparison
Control Section			
Control Section			The control section of the Rhino-Laryngo Videoscopes (ENF-VH/V3) were designed have the same control mechanism however they are designed to be handled with up-right functionality rather than a pistol and trigger grip. The difference in the ergonomic design does not raise new questions of safety and effectiveness This difference does not alter or change the indications for use or result in a new intended use.
Total Length	510 mm	500mm	Total length difference is due to change in design of the control section for the subject device. This difference does not alter or change the indications for use or result in a new intended use.
Insertion section			
Insertion Tube Diameter – Distal End	2.6 mm	2.6 mm	Same as predicate
Insertion Tube Diameter – Flexible Outer Tube	2.9 mm	2.9 mm	Same as predicate
Insertion Section Working Length	300 mm	300 mm	Same as predicate
Bending section			
Angulation Range	Up 130° / Down 130°	Up 130° / Down 130°	Same as predicate
Venting Connector			
Position	On LG connector	On LG connector	Same as predicate
Sterilization			
EO	Available	Available	Same as predicate
STERRAD NX	Available	Available	Same as predicate
STERRAD 100S	Available	Available	Same as predicate

Feature/ Technological Characteristics	Subject Device ENF-V3	Predicate Device ENF-V4	Comparison
Compatible processor/Light Source/Monitor			
Compatible Processor	OTV-S200/S300 OTV-S190 CV-170	OTV-S190 CV-170	For V3- qualified additional processor OTV-S200/S300. Compatibility of ENF-V3 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	CLV-S190 CLL-S1	CLV-S190 CLL-S1	Same as predicate
Compatible Monitor	OEV-262H LMD-X310ST* * This can be combined with only OTV-S300.	OEV-262H OEV-261H OEV-191H	For V3- qualified LMD-X310ST.Compatibility of ENF-V3 with LMD-XS310ST was demonstrated during electrical safety and electromagnetic compatibility testing described in Section 17 confirm that this monitor does not raise new questions of safety or effectiveness.

Indications for Use

RHINO-LARYNGO VIDEOSCOPES OLYMPUS ENF-V3 and ENF-VH are intended to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis. RHINO-LARYNGO VIDEOSCOPEs OLYMPUS ENF-V3 and ENF-VH are indicated for use within the nasal lumens and airway anatomy (including nasopharynx and trachea).

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
ANSI AAMI IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
ISO 15739:2017	Photography – Electronic still-picture imaging – Noise measurements
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. NonClinical Bench Testing

Item	Applicable Device	Contents
Thermal Safety	ENF-VH ENF-V3	Thermal safety performance test verified compliance to Protection against excessive temperature and other safety hazards of IEC 60601-2-18:2009-08.
Composite Durability	ENF-VH ENF-V3	The durability test against composite stress of mechanical stress demonstrates the subject device retains its safety and effectiveness against the stresses expected in its use-life.
Noise and Dynamic Range	ENF-VH ENF-V3	The substantial equivalence of Noise and Dynamic range between the subject device and predicate device connected with Video System Center / Light Source was confirmed and verified compliant to ISO 15739:2017.
Color Performance	ENF-VH ENF-V3	The color performance of the subject devices is confirmed as substantially equivalent to the predicate devices in the WLI and NBI observation mode.
Image Intensity Uniformity	ENF-VH ENF-V3	The image intensity uniformity of the subject devices is confirmed as substantially equivalent to the predicate devices.
Resolution	ENF-VH ENF-V3	The resolution of the subject device is confirmed as substantially equivalent to the predicate device.
Photobiological Safety	ENF-VH ENF-V3	The photobiological safety test verified compliance to IEC 32471:2006-07 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.

2. Animal Test

Animal testing was not applicable and not performed.

3. Biocompatibility Evaluation

Biocompatibility evaluation of the patient contacting materials of the RHINO-LARYNGO VIDEOSCOPES OLYMPUS ENF-V3 and ENF-VH (categorized as a surface medical device with mucosal membrane contact and limited contact (≤24 hours)) was successfully validated by testing on the subject devices according to ISO 10993-1 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing. The overall conclusion is that the Biological Risk associated with this device is acceptable for the intended use.

4. Sterilization, Shelf Life, Reprocessing

RHINO-LARYNGO VIDEOSCOPEs OLYMPUS ENF-V3 and ENF-VH and their reusable accessories are not sterilized before shipment. Before using these instruments for the first time and after using the endoscopes, the devices must be reprocessed according to the instructions given in the subject endoscope's companion Reprocessing Manual. All cleaning, disinfection, and sterilization methods were validated pursuant to *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. ENF-VH/V3 are 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
- Sterilization with STERRAD NX
- Sterilization with STERRAD 100S

5. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC performance testing have been confirmed for the subject devices. RHINO-LARYNGO VIDEOSCOPEs OLYMPUS ENF-V3 and ENF-VH were found to be in compliance with the relevant requirements noted below.

Standards	
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
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)

6. Software Verification and Validation Testing

Software testing has been performed and documented to be in compliance with the FDA guidance "*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*."

7. Risk Analysis

Risk management has been performed in accordance with ISO 14971:2007. In the risk management process, Olympus determined that 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." Refer to the risk management table for the RHINO-LARYNGO VIDEOSCOPEs OLYMPUS ENF-V3 and ENF-VH. To date, with respect to perceivable conditions in which the device would be subjected to a worst-case environmental 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

It is concluded that the safety and effectiveness of RHINO-LARYNGO VIDEOSCOPEs OLYMPUS ENF-V3 and ENF-VH are substantially equivalent to the legally marketed predicate devices, Rhino-Laryngo Videoscopes Olympus ENF-VH2 and ENF-V4 (K182102), respectively. Olympus claims substantial equivalence to the predicate devices based on evaluation of the on similarities in indications for use, design, materials, principle of operation, technological and performance characteristics, and operational characteristics. Differences are summarized in **Table 5-1 and 5-2 above**,

Conclusion

In summary, RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V3 and RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH are substantially equivalent to the predicate devices and present no new questions of safety or effectiveness.