February 6, 2019

Olympus Medical Systems Corp.
% Sheri Musgnung
Regulatory Affairs Manager
Olympus Surgical Technologies America
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610

Re: K182102
Trade/Device Name: Rhino-laryngo Videoscope Olympus ENF-VH2, Rhino-laryngo Videoscope Olympus ENF-V4
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB, NWB
Dated: January 4, 2019
Received: January 7, 2019

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/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,

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)*
K182102

Device Name
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH2
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V4

Indications for Use *(Describe)*
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).

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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February 4, 2019

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 Surgical Technologies America
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Center Valley, PA 18034-0610, USA
Phone: 484-896-3147
Fax: 484-896-7128
Email: sheri.musgnung@olympus.com

2 DEVICE IDENTIFICATION

■ Device Name: RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH2
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V4

■ Common Name: RHINO-LARYNGO VIDEOSCOPE

■ Regulation Number: 874.4760, 876.1500

■ Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories, Endoscope and accessories.

■ Regulatory Class: II

■ Product Code: EOB, NWB

■ Classification Panel: Ear Nose & Throat

3 PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
VISERA RHINO-LARYNGO VIDEOSCOPE PLYMPUS ENF TYPE V2 (EVIS EXERA II CV-180 SYSTEM)	OLYMPUS MEDICAL SYSTEMS CORP.	K061313

4 DEVICE DESCRIPTION

■ **General Description of the subject device**

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).

It mainly consists of four functional parts:

- video connection section including a video connector and video cable that connects the endoscope to the video system center for displaying images on compatible video monitors.
- light guide connector section that links the endoscope with light source and transmits light to the distal end of the endoscope.
- control section that operates endoscope such as controlling angulation to guide insertion and observation.
- insertion section that goes through and contacts with the nasal lumens and airway anatomy (including nasopharynx and trachea) under light guide.

■ **Principle of Operation**

a. Basic principle

- **Illumination light supply**

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.

- **Image construction**

The endoscope receives the reflected light from the inner lumen of a patient by objective lens at the distal end. The built-in CCD at the distal end converts the light to the electrical signal, and the signal is sent to the video system center via the electrical cable and the video connector of the endoscope. The endoscope transfers the image signal and displays the observation image on the screen.

- **Bending operation**

The UP/DOWN angulation control lever and bending section are connected with each other by 2 independent wires. It is possible to bend the bending section to the UP/DOWN direction by operating the UP/DOWN angulation control lever.

b. Technological characteristics

- **New control section**

The new control section of ENF-VH2 and ENF-V4 consists of a pistol grip shape. The new control section reduces the angle of the wrist and enables the insertion section to be directed to the nasal cavity of sitting patient even when the wrist and arm of the physician is in a relaxed situation.

- **New layout of switches**

By arranging the 3 switches of new ENT control section, physicians can easily push the 3 switches with only an index finger

- **Reduced total weight**

Newly developed configuration of control section and thinner and lighter universal cord leads to a reduction in the handling mass of the endoscope control section.

- **List of compatible equipment**

Table 1 Compatible equipment

	Model name	510(k) number
Endoscopes	ENF-V4	K182102 (this submission)
	ENF-VH2	K182102 (this submission)
VISERA ELITE video system center	OTV-S190	K111425
Video system center	CV-170	K122831
VISERA ELITE xenon light source	CLV-S190	K111425
Strobe LED Light source	CLL-S1	EXEMPT from Premarket Notification
Video monitors	OEV262H	K102379
	OEV261H	K954451
	OEV191H	K954451

5 INDICATIONS FOR USE

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).

6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The ENF-VH2 and ENF-V4 have the same technological characteristics and design as the predicate device except for the following new features:

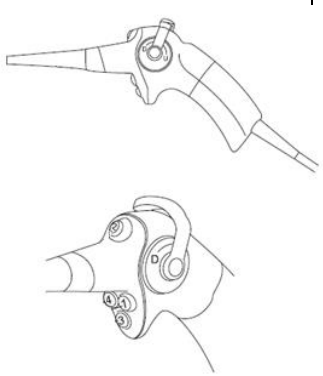
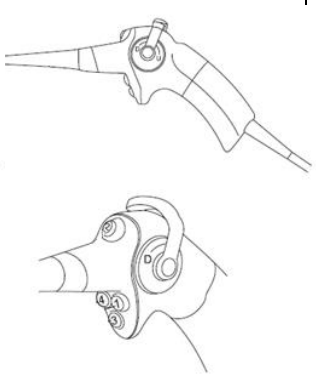
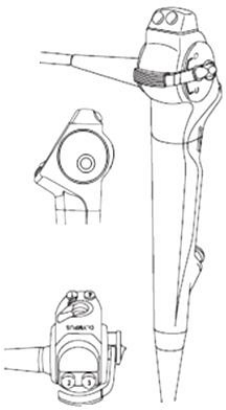
- Changes on optical system parameters (total number of pixels, resolution, etc.)
- Configuration modification of control section to improve operability
- Dimensional and material changes on the insertion section
- Extension of reprocessing methods
- Software implementation to correct the pixel defect

All other technological characteristics of both the subject and predicate devices are identical.

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 2 Device Comparison Table

Features	<Subject Device1> RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH2 #K182102	<Subject Device2> RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V4 #K182102	<Predicate Device> VISERA RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF TYPE V2 #K061313
Indications for use	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).	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).	This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic within the nasal lumens and airway anatomy (including nasopharyngeal and trachea).
Field of View	110°	90°	90°
Depth of Field	5-50mm	3.5-50mm	5-50mm
Direction of Forward View	0°(Forward viewing)	0°(Forward viewing)	0°(Forward viewing)
Outer Diameter of Distal End	φ3.9mm	φ2.6mm	φ3.2mm
Outer Diameter of Insertion Tube	φ3.6mm	φ2.9mm	φ3.4mm
Bending Section Angulation	UP:130° DOWN:130°	UP:130° DOWN:130°	UP:130° DOWN:130°
Working Length of insertion section	300mm	300mm	300mm

Features	<Subject Device1> RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH2 #K182102	<Subject Device2> RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V4 #K182102	<Predicate Device> VISERA RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF TYPE V2 #K061313
Configuration of Control section and location of scope switch			
NBI observation	Available	Available	Available
Reprocess with OER-Pro	available	available	unavailable
Sterilization with STERRAD	available	available	unavailable
Sterilization with V-PRO	available	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 ENF-VH2 and ENF-V4 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 ENF-VH2 and ENF-V4 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 ENF-VH2 and ENF-V4 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 ENF-VH2 and ENF-V4. 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 ENF-VH2 and ENF-V4 as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

- Thermal safety test
- Mechanical durability test
- Optical performance test
- Color performance test

6) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

7) Performance testing - Clinical

Clinical testing for ENF-VH2 and ENF-V4 as listed below was conducted to support the market claims.

- Evaluation for supporting evidence of marketing claim
- Meta-analysis

8) Risk analysis

Risk analysis for the ENF-VH2 and ENF-V4 was conducted in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result

of this risk analysis assessment.

8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the ENF-VH2 and ENF-V4 raise no new issue of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, efficacy and performance.