September 6, 2019

Olympus Medical Systems Corp.
% Daphney Germain-Kolawole
Project Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, Pennsylvania 18034-0610

Re: K183416
Trade/Device Name: Rhino-Laryngo Videoscope Olympus ENF-VT3
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB, NWB
Dated: August 7, 2019
Received: August 7, 2019

Dear Daphney Germain-Kolawole:

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 Srinivas Nandkumar, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183416

Device Name
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VT3

Indications for Use *(Describe)*

RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VT3:

This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment. This instrument is indicated for use within the nasal lumens and airway anatomy (including nasopharynx and trachea). This instrument is intended for use in a clinical or ambulatory medical environment.

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

1. GENERAL INFORMATION

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

■ Contact Person: Daphney Germain-Kolawole
Olympus Corporation of the Americas
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610
Phone: 484-896-5691
Fax: 484-896-7128
Email: daphney.germain-kolawole@olympus.com

■ Preparation Date: 9/6/2019

2. DEVICE IDENTIFICATION

■ Device Name RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VT3

■ 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, Gastroenterology/Urology

3. PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
VISERA RHINO-LARYNGO VIDEOSCOPE OLYMPUS XENF TYPE VTY1	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, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment. This instrument is indicated for use within the nasal lumens and airway anatomy (including nasopharynx and trachea).

It is mainly consisted of four functional parts:

- video connection section including video connector and video cable that connect the endoscope to the video system center for displaying images on compatible video monitors
- light guide connector section that links the endoscope with a light source and transmits light to the distal end of the endoscope
- control section that operates the endoscope such as controlling angulation to guide insertion and observation, activating suction by single-use suction valve and performing treatment by means of allowing EndoTherapy accessories to enter into the instrument channel.
- insertion section that goes through and contacts with the nasal lumens and airway anatomy (including nasopharynx and trachea) under the light guide.

■ **Principle of Operation**

a. Basic principle

- Illumination light supply

The endoscope receives the illumination light from the light source by the 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 the 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

UP/DOWN angulation control lever and RIGHT/LEFT angulation control lever and bending section are connected to each other by an independent wire. It is possible to bend in the up/down direction by operating the UP/DOWN angulation control lever, bend in theright/left direction by operating the RIGHT/LEFTLIGHT angulation control lever, respectively.

b. Technological characteristics

- 4-direction angulation capability

Distal end is possible to bend in the UP/DOWN direction up to 130° and RIGHT/LEFT direction up to 70°, respectively.

- User interface

In contrast to predicate device where the operations to combine the rotation of the device body and adjustment of angulation lever to reach an ideal observation site, this new subject device can alter the direction of the distal end by the angulation control levers solely to achieve the same observation effects and avoid potential damage caused by rotating the device body.

5.INDICATIONS FOR USE

This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment. This instrument is indicated for use within the nasal lumens and airway anatomy (including nasopharynx and trachea). This instrument is intended for use in a clinical or ambulatory medical environment.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The ENF-VT3 has the same technological characteristics and design as the predicate device except for the following new features:

1. Changes on the optical system parameters (total number of pixels, resolution, etc.)
2. Material change of insertion section
3. Incorporated 4-direction angulation capability
4. Modify user interface to add RIGHT/LEFT operation
5. Software implementation to correct the pixel defect

Comments on the difference

1. The key parameter of observation is the image resolution. The subject device has been designed to improve the image resolution compared to the predicate device. This improvement does not affect the indication use. Therefore, there is no problem in safety and effectiveness.
2. Biocompatibility test of the final finished form was conducted, and the results support safety and effectiveness of the changed material.
3. The distal end is possible to bend in the UP/DOWN direction up to 130° and RIGHT/LEFT direction up to 70° respectively. We performed a risk assessment and determined that the residual risk is acceptable.
4. Although it seems the angulation range has increased in the subject device for the addition of the RIGHT/LEFT angulation, which is more likely to damage adjacent tissues around the observation site, we would like to emphasize that even for the original predicate device, operators are capable of not only changing the angulation by the UP/DOWN control lever inherently set in the device, but also adjusting the direction of the distal end by rotating the whole device by force outside the patient. However, in contrast to the predicate device where the operation to combine the rotation of the device body and adjustment of angulation lever to reach an ideal observation site, this new subject device can alter the direction of the distal end by angulation control levers solely to achieve the same observation effects and avoid the potential damage caused by rotating the device body. In addition, bench test results also demonstrate that the fundamental

function of the subject device has no changes and will not influence safety and effectiveness, and also risk management results considering human factors show that the residual risk is acceptable.
5. The function of the pixel defect correction was validated and it does not cause any new issue of safety and effectiveness.

All other technological characteristics of both the subject and predicate device 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.

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-VT3 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-VT3 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
- Systemic Toxicity Study in Mice

3) Software verification and validation testing

Software verification and validation testing for the ENF-VT3 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-VT3. 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-VT3 as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

- Thermal safety test
- Mechanical durability test
- Resolution test
- Phototoxicity 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 analysis

Risk analysis for the ENF-VT3 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

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, the ENF-VT3 raises no new issue of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness and performance.