March 3, 2025

Olympus Medical Systems Corporation
Wendy Perrreault
Regulatory Affairs SME Consultant
Olympus Surgical Technologies of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K243380
Trade/Device Name: Visera S Video System Center Olympus Otv-s500 (olympus Otv-s500)
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: October 30, 2024
Received: October 30, 2024

Dear Wendy Perrreault:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shuchen Peng -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243380

Device Name

VISERA S VIDEO SYSTEM CENTER OLYMPUS OTV-S500 (OLYMPUS OTV-S500)

Indications for Use *(Describe)*

The VISERA S VIDEO SYSTEM CENTER OLYMPUS OTV-S500, when used with endoscopes, video endoscopes, camera heads, monitors and other ancillary equipment for endoscopic surgery, is intended to receive and process electronic signals transmitted from a video endoscope/camera head and output image signal to monitor.

Also, the VISERA S VIDEO SYSTEM CENTER OLYMPUS OTV-S500, when used with rhino-laryngeal stroboscopes, is intended to observe the intralaryngeal phenomenon of phonation (speech) for endoscopic observation to examine the correct functioning of the vocal apparatus (glottis) and to examine voice disorders.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

OLYMPUS

510(k) Summary: K243380

1. COMPANY INFORMATION

- **Applicant**

OLYMPUS MEDICAL SYSTEMS CORPORATION
2951 Ishikawa-cho, Hachioji-shi
Tokyo 192-8507, Japan
FDA Establishment Registration #: 8010047

- **Official Correspondent**

Wendy Perreault
c/o Olympus Surgical Technologies of the Americas
800 West Park Drive
Westborough, MA 01581
Cell: 404-542-5854
Email: wendy.perreault@olympus.com

- **Manufacturing Site**

SHIRAKAWA OLYMPUS CO., LTD.
3-1 Okamiyama, Odakura
NISHIGO-MURA
NISHISHIRAKAWA-GUN Fukushima, JAPAN 961-8061

- **Date Prepared:** 7 February 2025

2. PRODUCT INFORMATION

Trade Name: VISERA S VIDEO SYSTEM CENTER OLYMPUS OTV-S500 (OLYMPUS OTV-S500)

Common Name: Nasopharyngoscope (Flexible or Rigid)

Classification Name: Nasopharyngoscope (Flexible or Rigid) and Accessories

Classification Number: 874.4760

Product Code Names: Nasopharyngoscope (Flexible or Rigid) and Accessories; Bronchoscope (Flexible or Rigid) and Accessories; Endoscopes and Accessories; Laryngostroboscope

Product Codes: EOB, EOQ, NWB, EQL

Regulatory Class: II

Classification Panel: Ear, Nose & Throat (ENT)

3. PREDICATE DEVICE

The Subject device is equivalent to the Predicate device listed below in **Table 1**.

Table 1: Predicate device of OLYMPUS OTV-S500

Device name	510(k) Submitter	510(k) No.
PENTAX Medical Imaging Systems with PVK-J10 Camera Head (PENTAX Medical EPK-3000 Video Imaging System)	PENTAX of America, Inc.	K220465

The Predicate device has not been subject to a design-related recall.

The Reference devices to the Subject device are listed in **Table 2**:

Table 2: Reference devices for OLYMPUS OTV-S500

Device name	510(k) Submitter	510(k) No.
OLYMPUS OTV-S500 (Submitted with urology/ gynecology scopes)	OLYMPUS MEDICAL SYSTEMS CORP.	K241371
OLYMPUS OTV-S190 (Video System Center) with CLV-S190 (Light source for WLI/NBI observation)	OLYMPUS MEDICAL SYSTEMS CORP.	K111425
OLYMPUS OTV-S190 (Video System Center) with CLL-S1 (WA97010A) (Light source for Stroboscope)	OLYMPUS MEDICAL SYSTEMS CORP.	K111425 (Video System Center) (Light Source is 510[k] exempt)

4. DEVICE DESCRIPTION

The OLYMPUS OTV-S500 is a "universal platform" which offers compatibility with various endoscopes for different medical specialties and enables efficient operation to meet the clinical needs of the ENT field; the device has been cleared by FDA for use with OLYMPUS urology/gynecology endoscopes (including CYF-VH, CYF-VHR, URF-V2, URF-V2R, URF-V3, URF-V3R, WA2T400A, WA2T412A, WA2T430A, WA2T43WA, WA2T470A, WA2UR11A, WA2UR12A, WA2UR13A, WA2UR14A, WA2UR21A, WA2UR22A, WA2UR23A, WA2UR31A, WA2UR32A, CYF-5, CYF-5R, URF-P6, URF-P6R, URF-P7, URF-P7R and HYF-XP) under K241371.

The OLYMPUS OTV-S500 consists of electrical circuit boards, electrical units (cooling fan, unit power supply, and control panel), harnesses between circuit boards, and optical components (lens and optical filter). A microprocessor is built into the OLYMPUS OTV-S500 which controls processing of observation images, user interface (front panel switch, indicator LEDs, warning buzzer etc.) and menu. These functions are implemented in the embedded software. Scopes including flexible videoscopes or fiberscopes and rigid videoscopes with camera heads and light source are directly connected to the Subject system. When connected, the endoscope (fiberscopes and rigid videoscope without camera head) acquires and displays images directly to the user or output onto a monitor when using a flexible endoscope or scope and camera head.

The Subject devices submitted for clearance include one (1) major component: the Video System Center (OLYMPUS OTV-S500) with Foor Holder (MAJ-2552), and five (5) optional accessories: an HDMI cable (MAJ-2551); the OTV-S500 Upgrade Pack Strobe (MAJ-2547), which activates the stroboscopy function of the OTV-S500; an Air Microphone (MAJ-2548); a Throat Microphone (MAJ-2549); and the Microphone Extension Cable (MAJ-2550).

The OLYMPUS OTV-S500 is compatible with the following OLYMPUS ENT endoscopes: ENF-VH, ENF-VH2, ENF-V3, ENF-V4, ENF-VT3, ENF-XP, ENF-GP2, WA4KS400, WA4KS430, WA4KS431, WA4KS445, WA4KS446, WA4KS470, WA4KS471, WA96100A and WA96105A.

5. INDICATIONS FOR USE

The VISERA S VIDEO SYSTEM CENTER OLYMPUS OTV-S500, when used with endoscopes, video endoscopes, camera heads, monitors and other ancillary equipment for endoscopic surgery, is intended to receive and process electronic signals transmitted from a video endoscope/camera head and output image signal to monitor.

Also, the VISERA S VIDEO SYSTEM CENTER OLYMPUS OTV-S500, when used with rhino-laryngeal stroboscopes, is intended to observe the intralaryngeal phenomenon of phonation (speech) for endoscopic observation to examine the correct functioning of the vocal apparatus (glottis) and to examine voice disorders.

OLYMPUS

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Compared to the Predicate device, the Subject device offers similar functions including stroboscopy. A detailed comparison of the technological characteristics of the devices is provided in **Table 3** below. These differences in technological characteristics do not raise new questions of safety or effectiveness.

Table 3: Subject and Predicate Comparison of Technological Characteristics

	OLYMPUS OTV-S500 (Subject Device)	**PENTAX Medical Imaging Systems with PVK-J10 Camera Head (PENTAX Medical EPK-3000 Video Imaging System) (Predicate Device)**
Indications for Use	The VISERA S VIDEO SYSTEM CENTER OLYMPUS OTV-S500, when used with endoscopes, video endoscopes, camera heads, monitors and other ancillary equipment for endoscopic surgery, is intended to receive and process electronic signals transmitted from a video endoscope/camera head and output image signal to monitor. Also, the VISERA S VIDEO SYSTEM CENTER OLYMPUS OTV-S500, when used with rhino-laryngeal stroboscopes, is intended to observe the intralaryngeal phenomenon of phonation (speech) for endoscopic observation to examine the correct functioning of the vocal apparatus (glottis) and to examine voice disorders.	PENTAX Medical EPK-3000 Video Processor is intended to be used with the PENTAX Medical camera heads with PENTAX sinuscopes (8890, 8891, 8892, 8893), PENTAX Medical VNL8-J1O, VNL1-J10, and VNL15-J1O endoscopes, PENTAX Medical Laryngeal Strobe, video monitors and other ancillary equipment for ENT endoscopic observation and ENT diagnosis, treatment and video observation with or without stroboscopy. The PENTAX Medical EPK-3000 Video Processor includes PENTAX i-Scan™, a digital, post-processing imaging enhancement technology. i-Scan is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling.
Front panel (Operation)	Available	Available
Analog HDTV signal output	Not available	Not available
Analog SDTV signal output	Not available	RGB, Y/C, composite
Digital signal output	SDI (HD-SDI or 3G-SDI) HDMI (1080P)	DVI
White balance adjustment	Available	Available
Standard color chart output	The “Color bar” can be displayed.	Not available
Color tone adjustment	Color Hue / Saturation adjustment ±5 steps for Magenta/ Red/ Orange/ Yellow color	Available
Contrast	Image contrast enhancement can be set (ON, OFF)	Available

	OLYMPUS OTV-S500 (Subject Device)	PENTAX Medical Imaging Systems with PVK-J10 Camera Head (PENTAX Medical EPK-3000 Video Imaging System) (Predicate Device)
Image enhancement setting	Structural enhancement Edge enhancement	Available
Switching the enhancement modes	Available	Available
Image size selection	Available	Available
Freeze	Available	Available
Pre-freeze	Available	Available
Compatible scopes/Camera head	Video endoscopes for ・ Rhino-Laryngology Camera head for ・ Rhino-Laryngology Telescope/Fiber scope for ・ Rhino-Laryngology	PENTAX Medical camera heads with PENTAX sinuscopes and endoscopes for ENT endoscopic observation and ENT diagnosis and treatment
Stroboscopy function	Available	Available
Dimensions (maximum)	308(W) x 157(H) x 461(D) mm	350(W) x 180(H) x 485(D) mm
Weight	10.6kg	13.0kg
Examination Lamp	LED (White LED: 1 and Violet LED: 1)	Xenon 150W
Rated input	150VA	360VA

7. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Results of the following testing support the safety and performance of the Subject device and demonstrate its equivalence to the Predicate device and applicable Reference devices; all testing passed/met the acceptance criteria, demonstrated compliance with the cited standards and FDA Guidance shown below, and supported equivalent safety and performance to the Predicate device:

- Performance Testing – Bench (including Subject and Reference device testing of Field of View [in compliance with ISO 8600-3:2019); Resolution; Image Noise and Dynamic Range [tested according to ISO 15739:2017]; Brightness; Image Intensity Uniformity; Color Performance [including analysis with the FDA Color Performance Review (CPR) Tool for Endoscopy Devices]; Latency; Contrast Enhancement; Depth of Field; Optical Magnification and Distortion; and Human Use Factors). Test results support performance of the Subject device with compatible endoscopes.
- Electrical Safety/EMC Testing (ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]; ANSI AAMI IEC 60601-1-2 [Including AMD 1:2021]; IEC 60601-2-18: Edition 3.0 2009-08; IEC TR

60601-4-2 Edition 1.0 2016-05; IEC 60601-1-6 Edition 3.2 2020-07 Consolidated Version)

- Software Validation/Cybersecurity (IEC 62304 Edition 1.1 2015-06 Consolidated Version; ISO 14971:2019; FDA Guidance Document *Content of Premarket Submissions for Device Software Functions – Guidance for Industry and Food and Drug Administration Staff*, issued on June 14, 2023; FDA Guidance Document *Off-the-Shelf Software Use in Medical Devices – Guidance for Industry and Food and Drug Administration Staff*, issued August 11, 2023; FDA Guidance Document *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*, issued on September 27, 2023)

8. SUMMARY OF CLINICAL PERFORMANCE DATA

No clinical data were collected to support performance of the Subject device.

9. CONCLUSION

The results of non-clinical performance testing demonstrate that the Subject device is as safe and effective as the Predicate device to support a substantial equivalence determination.