July 3, 2024

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

Re: K241371
Trade/Device Name: VISERA S VIDEO SYSTEM CENTER OLYMPUS OTV-S500 (OLYMPUS OTV-S500)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET, NTN, NWB
Dated: May 14, 2024
Received: May 15, 2024

Dear Wendy Perreault:

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.

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,

Reginald K. Avery -S

for Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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.

510(k) Number *(if known)*
K241371

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.

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.

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OLYMPUS

510(k) Summary: K241371

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
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Cell: 404-542-5854
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- **Manufacturing Site**

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

- **Date Prepared:** 2-July-2024

2. PRODUCT INFORMATION

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

Common Name: Video System Center

Classification Name: Endoscope and accessories

Classification Number: 876.1500

Product Code Names: Endoscopic Video Imaging System/Component, Gastroenterology-Urology, LED Light Source, and Endoscope, Accessories, Narrow Band Spectrum

Product Codes: FET, NTN, NWB

Regulatory Class: II

Classification Panel: Gastroenterology / Urology

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.
CV-170 VIDEO SYSTEM CENTER	OLYMPUS MEDICAL SYSTEMS CORP.	K122831

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

4. DEVICE DESCRIPTION

The OLYMPUS OTV-S500 is a “universal platform” which offers compatibility with various endoscopes for different medical specialties and enables operation to meet the clinical needs in the fields of urology and gynecology. The Subject device is intended to be used in conjunction with ancillary equipment for endoscopic diagnosis, treatment and observation.

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); and two (2) auxiliary components: Foot Holder (MAJ-2552)

for the OLYMPUS OTV-S500 that are shipped with the Video System Center, and an optional HDMI cable (MAJ-2551).

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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Compared to the Predicate device, the Subject device offers the same functions but uses newer technology and incorporates additional features, such as digital HDMI output and additional color tone adjustment. A detailed comparison of the technological characteristics of the devices is provided in the Table below. These differences in technological characteristics do not raise new questions of safety or effectiveness.

	OLYMPUS OTV-S500 (Subject Device)	**OLYMPUS CV-170 (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.	This video system center is intended to be used with OLYMPUS video converter, camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation.
Front panel (Operation)	Available	Available
Analog HDTV signal output	Not available	Either RGB (1080/60I) or YPbPr (1080/60I) output
Analog SDTV signal output	Not available	VBS composite (480/60I: NTSC), Y/C (480/60I: NTSC), and RGB (480/60I: NTSC); simultaneous outputs possible.
Digital signal output	SDI (HD-SDI or 3G-SDI) HDMI (1080P)	SDI (HD-SDI or SD-SDI) DVI (WUXGA,1080P or SXGA can be selected)
White balance adjustment	Available	Available
Standard color chart output	The “Color bar” can be displayed.	The “Color bar” or the “50% white” screen can be displayed.
Color tone adjustment	Color Hue / Saturation adjustment ±5 steps for Magenta/ Red/ Orange/ Yellow color	Red adjustment: ±8 steps Blue adjustment: ±8 steps Chroma adjustment: ±8 steps
Automatic Gain control (AGC)	Available	Available

	OLYMPUS OTV-S500 (Subject Device)	**OLYMPUS CV-170 (Predicate Device)**
Contrast	Image contrast enhancement can be set (ON, OFF)	The image contrast can be set to one of the following three modes (Normal, High, Low)
Noise reduction	Available	Available
Image enhancement setting	Structural enhancement Edge enhancement	Structural enhancement Edge enhancement
Switching the enhancement modes	Available	Available
Image size selection	Available	Available
Freeze	Available	Available
Pre-freeze	Available	Available
Optical-digital observation	NBI observation	NBI observation
Compatible scopes/Camera head	Video endoscopes for ・ Urology ・ Obstetrics and gynecology Camera head for ・ Urology ・ Obstetrics and gynecology Telescope/Fiber scope for ・ Urology ・ Obstetrics and gynecology	・Flexible video scopes including, but not limited to, Gastroscope Colonoscope Duodenoscope Small intestinal scope Sigmoidoscope Bronchoscope Cysto-nephro scope Choledochoscope Rhino-laryngo scope Esophagoscope Ureteroscope Ureterorenoscope ・Rigid scopes ・Fiber scopes ・Video converter ・Camera head
Dimensions (maximum)	308(W) x 157(H) x 461(D) mm	309(W) x 156(H) x 442(D) mm
Weight	10.6kg	11.0kg
Examination Lamp	LED (White LED: 1 and Violet LED: 1)	LED (White LED: 1 and Violet LED: 1)
Rated input	150VA	200VA

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; 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 Predicate 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; and Contrast Enhancement). The Subject device performed equivalently to the Predicate device, and 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.