November 12, 2025

Olympus Medical Systems Corp.
% Darlene Hull
Program Manager, Regulatory Affairs
Olympus Surgical Technologies of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K251336
Trade/Device Name: VISERA ELITE III Video System Center Olympus OTV-S700 (OTV-S700); VISERA ELITE III Light Source Olympus CLL-S700 (CLL-S700); 4K Camera Head Olympus CH-S700-XZ-EA (CH-S700-XZ-EA)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN, FET, NWB
Dated: April 30, 2025
Received: April 30, 2025

Dear Darlene Hull:

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,

Jessica Carr -S

Jessica Carr, PhD
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control 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)*
K251336

Device Name
VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 (OTV-S700);
VISERA ELITE III LIGHT SOURCE OLYMPUS CLL-S700 (CLL-S700);
4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA (CH-S700-XZ-EA)

Indications for Use *(Describe)*
The VISERA ELITE III Surgical Imaging System is intended to provide real-time visible and near infrared fluorescence imaging.

Upon intravenous administration and use of ICG consistent with its approved label, VISERA ELITE III Surgical Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the VISERA ELITE III Surgical Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Upon interstitial administration and use of ICG consistent with its approved label, the VISERA ELITE III Surgical Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

The VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 is intended to process electronic signals transmitted from a video endoscope/camera head and output image signal to monitor, and to be used with endoscopes, video endoscopes, camera heads, light sources, monitors and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

The VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700 is intended to provide light to an endoscope/video endoscope in order to process electronic signals transmitted from them and output image signal to monitor, and to be used with endoscopes, video endoscopes, camera heads, video system centers, monitors and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

The 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA is intended to be used with endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

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

Company Information

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  Establishment Registration No: 8010047
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  Nishishirakawa-gun, Fukushima 961-8061, Japan
- Date Prepared: 30-Apr-2025

Product Information

- Trade Name: VISERA ELITE III Surgical Imaging System
- Common Name: Endoscopic Imaging System
- Classification Name: Endoscope and Accessories
- Regulation Number: 876.1500
- Regulation Name: Endoscope and Accessories
- Regulatory Class: II
- Product Code(s): OWN (Confocal Optical Imaging)
  FET (Endoscopic Video Imaging System/Component, Gastroenterology-Urology)
  NWB (Endoscope, Accessories, Narrow Band Spectrum)
- Classification Panel: Office of Surgical and Infection Control Devices (OHT4)
  Division of General Surgery Devices (DHT4A)

Predicate Device

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
Karl Storz ICG Imaging System	Karl Storz	K202925

■ **Reference device**

Device name	510(k) Submitter	510(k) No.
VISERA ELITE II Infrared Imaging System	Olympus Medical Systems Corp.	K200542

Product Information

The VISERA ELITE III Surgical Imaging System is intended to be used with ancillary equipment for endoscopic diagnosis, treatment, and observation and supports the function of high definition (HD) videoscopes and is Camera Head (CH) compatible.

The following subject devices of the OLYMPUS VISERA ELITE III Surgical Imaging System are identical to and unchanged from the VISERA ELITE III Surgical Imaging System (K242067):

- **VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 (Model Number: OLYMPUS OTV-S700)** – OLYMPUS OTV-S700 is a video system center that processes electronic signals transmitted from a video endoscope or a camera head and outputs the image signal to a monitor.
    - **OTV-S700 3D UPGRADE PACK (Model Number: OLYMPUS MAJ-2511)** – A function activation portable memory key accessory that unlocks the 3D software function when connected with VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 to enable 3D observation mode.
- **VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700 (Model Number: OLYMPUS CLL-S700)** – A LED light source that provides examination light to a video endoscope and a camera head.
- **4K Camera Head OLYMPUS CH-S700-XZ-EA (Model Number: OLYMPUS CH-S700-XZ-EA)** – A 4K Inline camera head is intended to be used with Olympus endoscopes, the video system center, and other ancillary equipment for the visualization of internal organs (Endoscopic diagnosis), treatment and observation.

INDICATIONS FOR USE

Device	Indications for Use
VISERA ELITE III Surgical Imaging System	The VISERA ELITE III Surgical Imaging System is intended to provide real-time visible and near infrared fluorescence imaging. Upon intravenous administration and use of ICG consistent with its approved label, VISERA ELITE III Surgical Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the VISERA ELITE III Surgical Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization. Upon interstitial administration and use of ICG consistent with its approved label, the VISERA ELITE III Surgical Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.
VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700	The VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 is intended to process electronic signals transmitted from a video endoscope/camera head and output image signal to monitor, and to be used with endoscopes, video endoscopes, camera heads, light sources, monitors and other ancillary equipment for endoscopic diagnosis, treatment, and observation.
VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700	The VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700 is intended to provide light to an endoscope/video endoscope in order to process electronic signals transmitted from them and output image signal to monitor, and to be used with endoscopes, video endoscopes, camera heads, video system centers, monitors and other ancillary equipment for endoscopic diagnosis, treatment, and observation.
4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA	The 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA is intended to be used with endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

Comparison of Technological Characteristics

Compared to the predicate devices, the changes are limited to the addition of the following functions to the OLYMPUS VISERA ELITE III product offering:

- Expansion of the VISERA ELITE III Surgical Imaging System's indications for use statement to include:
  - Near-infrared fluorescence imaging using intravenous administration and use of ICG consistent with its approved label, and
  - Intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.
- OTV-S700 Upgrade Pack IR (Model Number: MAJ-2512), a function open portable memory key accessory that unlocks the infrared (IR) software function when connected with the VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 to enable the IR observation mode. Identical to how 3D observation mode is activated for OLYMPUS OTV-S700 in K242067.
- Reprocessing sterilization validation with STERRAD and V-PRO maX2 for the 4K Camera Head OLYMPUS CH-S700-XZ-EA in addition to the reprocessing validation established in K242067.

There are no changes in contents of the indications for use, conditions of use, compatible components or accessories to be marketed/used with the device, or device specifications for VISERA ELITE III Surgical Imaging System.

A side-by-side comparison of the subject devices and the predicate devices is provided in the tables below.

Table 01. Comparison of the technological characteristics of VISERA ELITE III Surgical Imaging System to the Predicate Devices

Table 01. Comparison of the technological characteristics of VISERA ELITE III Surgical Imaging System to the Predicate Devices**Feature/ Technological Characteristics**	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Substantial Equivalence Discussion**
Regulatory				
System Name	VISERA ELITE III Surgical Imaging System	Karl Storz ICG Imaging System	VISERA ELITE II Infrared Imaging System	Not Applicable
Legal Manufacturer	Olympus Medical Systems Corp.	KARL STORZ	Olympus Medical Systems Corp.	Not Applicable
Regulatory Decision	This Submission	K202925	K200542	Not Applicable
Regulation No.	876.1500	876.1500 882.1480	876.1500	Substantially equivalent to the primary and secondary predicate devices. The VISERA ELITE III Surgical Imaging System does not claim the neurological endoscope regulations because it is not intended for neurological indications.
Regulation Name	Endoscope and accessories	Endoscope and accessories Neurological endoscopes	Endoscope and accessories	
Product Code	OWN, FET, NWB	OWN, GWG	OWN, FET, GCJ, HET, NWB	Substantially equivalent to the primary and secondary predicate devices. The VISERA ELITE III Surgical Imaging System does not claim the product codes GCJ and HET because the submission does not include laparo-scopes as subject devices. The VISERA ELITE III Surgical Imaging System does not claim the product code GWG because it is not intended for neurological indications.
Regulatory Class	II	II	II	Same as predicates
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Same as predicates

Table 01. Comparison of the technological characteristics of VISERA ELITE III Surgical Imaging System to the Predicate Devices**Feature/ Technological Characteristics**	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Substantial Equivalence Discussion**
Indications for Use (emphasis added to demonstrate similarities)	The VISERA ELITE III Surgical Imaging System is intended to provide real-time visible and near infrared fluorescence imaging. Upon intravenous administration and use of ICG consistent with its approved label, VISERA ELITE III Surgical Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the VISERA ELITE III Surgical Imaging System is intended for use with standard of care white light and, when indicated, intraoperative	The KARL STORZ ICG Imaging System is intended to provide real-time visible (VIS) and near-infrared (NIR) fluorescence imaging. Upon intravenous administration and use of ICG consistent with its approved label, the KARL STORZ Endoscopic ICG System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the KARL STORZ Endoscopic ICG System is intended for use with standard	The VISERA ELITE II Infrared Imaging System is intended to provide real-time endoscopic visible and near infrared fluorescence imaging. The VISERA ELITE II Infrared Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the VISERA ELITE II Infrared Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.	Substantially equivalent to the primary and secondary predicate devices. The VISERA ELITE III Surgical Imaging System includes real-time endoscopic visible and near infrared fluorescence imaging enabling surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts identical to the primary and secondary predicate devices. The VISERA ELITE III Surgical Imaging System is a non-combination product indicated for use with intravenous/interstitial indocyanine green (ICG) consistent with its approved label and is intended to provide real-time and near infrared fluorescence imaging, identical to the primary predicate device. The VISERA ELITE III Surgical Imaging System indications for use includes performance of intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes, identical to the primary predicate device.

Table 01. Comparison of the technological characteristics of VISERA ELITE III Surgical Imaging System to the Predicate Devices**Feature/ Technological Characteristics**	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Substantial Equivalence Discussion**
	cholangiography. The device is not intended for standalone use for biliary duct visualization. Upon interstitial administration and use of ICG consistent with its approved label, the VISERA ELITE III Surgical Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization. Additionally, the KARL STORZ Endoscopic ICG System enables surgeon to perform minimally invasive cranial neurosurgery in adults and pediatrics and endonasal skull base surgery in adults and pediatrics > 6 years of age using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion using near infrared imaging. The KARL STORZ VITOM II ICG System is intended for capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method		The VISERA ELITE III Surgical Imaging System does not claim indications for use for minimally invasive cranial neurosurgery in adults and pediatrics or adjunctive evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures. These differences are not a change from prescription (Rx) use to over the counter (OTC) use. Further, this change does not describe a new disease, condition, or patient population that the device is intended in diagnosing, treating, preventing, curing, or mitigating. A risk-based assessment of the differences does not identify any new risks or significantly modified existing risks. Therefore, there are no substantial differences among the system indications for use statements that affect the safety and effectiveness.

Table 01. Comparison of the technological characteristics of VISERA ELITE III Surgical Imaging System to the Predicate Devices**Feature/ Technological Characteristics**	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Substantial Equivalence Discussion**
		for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures. The VITOM II ICG System is intended to provide a magnified view of the surgical field in standard white light. <u>Upon interstitial administration and use of ICG consistent with its approved label, the KARL STORZ Endoscopic ICG System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes</u>.		
Specifications				
IR Observation Mode	Available. Select and display one of the three (3) modes: 1. "IR+WLI" Overlay white light image and IR image,	Available. Select and display one of the three (3) modes: 1. "Overlay" Overlay white light image and IR image,	Available. Select and display one of the two (2) color modes	Substantially equivalent to the primary and secondary predicate devices.

Table 01. Comparison of the technological characteristics of VISERA ELITE III Surgical Imaging System to the Predicate Devices**Feature/ Technological Characteristics**	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Substantial Equivalence Discussion**
	2. "IR+M" Overlay magenta colored reflected light image and IR image, 3. "IR only" IR image only	2. "Intensity Map" Overlay white light image and IR image that is color-changed by fluorescence signal-intensity, 3. "Monochromatic" IR image only	1. "Color mode 1" Overlay magenta colored reflected light image and IR image, 2. "Color mode 2" IR images only	
Image sensor for IR image	CMOS imager	CMOS imager	CMOS imager	Same as predicate devices
Light Source for IR image	IR LED (700-780nm)	IR LED (720-810nm)	Xenon + Filter	Same as primary predicate
IR image resolution	4K (up to 3840 x 2160)	4K (up to 3840 x 2160)	HD (1920 x 1080)	Same as primary predicate

Table 02. Comparison of the technological characteristics of VISERA ELITE III VIDEO SYSTEM CENTER to the Predicate and Reference Devices

Feature/ Technological Characteristics	**Subject Device**	**Predicate Device**	**Reference Device**	**Substantial Equivalence Discussion**
Regulatory				
Device Name	VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700	VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700	VISERA ELITE II VIDEO SYSTEM CENTER W/LIGHT SOURCE OLYMPUS OTV-S300	Not Applicable
Model Number	OLYMPUS OTV-S700	OLYMPUS OTV-S700	OLYMPUS OTV-S300	Not Applicable

Feature/ Technological Characteristics	Subject Device	Predicate Device	Reference Device	Substantial Equivalence Discussion
Legal Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.	Same as predicate
Regulatory Decision	This submission	K242067	K202646	Not Applicable
Regulation No.	876.1500	876.1500	876.1500	Same as predicate
Regulation Name	Endoscope and accessories	Endoscope and accessories	Endoscope and accessories	Same as predicate
Product Code	FET, NWB	FET, NWB	FET, NWB	Same as predicate
Regulatory Class	II	II	II	Same as predicate
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology	Gastroenterology/Urology	Same as predicate
Indications for Use (emphasis added to demonstrate similarities)	The VISERA ELITE III VIDEO SYSTEM CENTER is intended to process electronic signals transmitted from a video endoscope/camera head and output image signal to monitor, and to be used with endoscopes, video endoscopes, camera heads, light sources, monitors and other ancillary equipment for endoscopic diagnosis, treatment, and observation.	The VISERA ELITE III VIDEO SYSTEM CENTER is intended to process electronic signals transmitted from a video endoscope/camera head and output image signal to monitor, and to be used with endoscopes, video endoscopes, camera heads, light sources, monitors and other ancillary equipment for endoscopic diagnosis, treatment, and observation.	This video system center is intended to be used with OLYMPUS camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation.	Same as predicate
Specifications				
Main Function	Video System Center	Video System Center	Video System Center and Light Source	Same as predicate
Rated Voltage	AC 100-240V/ 50-60Hz	AC 100-240V/ 50-60Hz	AC 100V/ 50-60Hz	Same as predicate
Rated Input	<170VA	<170VA	400VA	Same as predicate
Dimensions (Max.)	Width: 390 mm Height: 198 mm Depth: 500 mm	Width: 390 mm Height: 198 mm Depth: 500 mm	Width: 383 mm Height: 199 mm Depth: 506 mm	Same as predicate
Weight	12.1 kg	12.1 kg	19.3 kg	
2D Observation	Available	Available	Available	Same as predicate

Feature/ Technological Characteristics	Subject Device	Predicate Device	Reference Device	Substantial Equivalence Discussion
3D Observation	Available with the accessory MAJ-2511	Available with the accessory MAJ-2511	Available	Same as predicate
IR Observation	Available with the accessory MAJ-2512	Not Applicable	Available	IR Observation is not a new or novel feature in endoscopic systems and is not a change that describes a new disease, condition, or patient population. The legally marketed reference device, OLYMPUS OTV-S300, supports the addition of this technological characteristic in the subject device, OLYMPUS OTV-S700. Identical to subject device, the reference device is intended for endoscopic diagnosis, treatment and video observation. The reference device includes IR capability, identical to the subject device. IR observation with the reference device is available to the end user when connected to the IR light source, OLYMPUS CLV-S200-IR (K200542). In comparison, the subject device is delivered to the end user with IR Observation as a "locked" feature that is activated by connecting the portable USB key accessory (OTV-S700 Upgrade Pack IR, MAJ-2512) and performing the software upgrade to "unlock" the feature. Both the reference device and the subject device are provided to the end user with the IR functionality unavailable to the end user, until connected to another device to enable the feature. While IR Observation is not available to the end user in the predicate device, using a portable USB key accessory to "unlock" and activate an observation function is substantially equivalent predicate device accessory, (OTV-S700 Upgrade Pack 3D, MAJ-2511). The difference in how the function is made available to the end use does not change the system indications for use, or substantially impact the technological characteristics or raise new or different questions with respect to safety and effectiveness compared to the predicate device.
Near IR Observation	Available at 2D Observation	Not Applicable	Available at 2D Observation	Near IR Observation at 3D Observation is an additional feature introduced with the subject device. The Near IR Observation feature is unavailable in the predicate device because IR Observation is "locked" to the end user.

Feature/ Technological Characteristics	Subject Device	Predicate Device	Reference Device	Substantial Equivalence Discussion
				This feature is not a change to the system indications for use and does not substantially impact the technological characteristics or raise new or different questions with respect to safety and effectiveness compared to the predicate device.
WLI Observation	Available	Available	Available	Same as predicate
NBI Observation	Available	Available	Available	Same as predicate
HDR Observation	Available	Available	Not Available	Same as predicate
Iris Area Observation	Available	Available	Available	Same as predicate
Laser Mode Observation	Available	Available	Available	Same as predicate
Automatic Gain Control	Available	Available	Available	Same as predicate
Front Panel (Operation)	Touch Panel	Touch Panel	Touch Panel	Same as predicate
Fog Free Function	Available	Available	Available	Same as predicate
Compatible Endoscopes	Legacy 2D, 3D, and IR endoscopes	Legacy 2D and 3D endoscopes	Legacy IR endoscopes	Substantially equivalent to the predicate and reference devices. IR Observation is an available feature in OLYMPUS OTV-S300, a reference device that supports this technological characteristic in the subject device. IR Observation is not a new or novel feature in endoscopic systems. The VISERA ELITE III Surgical Imaging System expands the indications for use to include near infrared fluorescence imaging.

Table 03. Comparison of the technological characteristics of VISERA ELITE III LED LIGHT SOURCE to the Predicate Device

Feature/ Technological Characteristics	Subject Device	Predicate Device	Reference Device	Substantial Equivalence Discussion
Regulatory				
Device Name	VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700	VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700	Power LED Rubina Light Source TL400	Not Applicable
Model Number	OLYMPUS CLL-S700	OLYMPUS CLL-S700	TL400	Not Applicable

Feature/ Technological Characteristics	Subject Device	Predicate Device	Reference Device	Substantial Equivalence Discussion
Legal Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.	KARL STORZ	Not Applicable
Regulatory Decision	This submission	K242067	K202925	Not Applicable
Regulation No.	876.1500	876.1500	876.1500	Same as predicate
Regulation Name	Endoscope and accessories	Endoscope and accessories	Endoscope and Accessories	Same as predicate
Product Code	FET, NWB	FET, NWB	OWN, GWG	Same as predicate
Regulatory Class	II	II	II	Same as predicate
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology	General & Plastic Surgery	Same as predicate
Indications for Use (emphasis added to demonstrate similarities)	The VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700 is intended to provide light to an endoscope/video endoscope in order to process electronic signals transmitted from them and output image signal to monitor, and to be used with endoscopes, video endoscopes, camera heads, video system centers, monitors and other ancillary equipment for endoscopic diagnosis, treatment, and observation.	The VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700 is intended to provide light to an endoscope/video endoscope in order to process electronic signals transmitted from them and output image signal to monitor, and to be used with endoscopes, video endoscopes, camera heads, video system centers, monitors and other ancillary equipment for endoscopic diagnosis, treatment, and observation.	NIR/ICG fluorescent light sources are intended for generating light in endoscopic and microscopic diagnostic examinations and in surgical procedures. Light sources are used for illumination during endoscopic, open or microscopic procedures. Additionally they are used for excitation during near infrared fluorescence imaging.	Same as predicate
Specifications				
Main Function	Light Source	Light Source	Light Source	Same as predicate
Rated Voltage	AC 100-240V/ 50-60Hz	AC 100-240V/ 50-60Hz	100 - 125 / 220 - 240 VAC 50/60 Hz	Same as predicate
Rated Input	215VA	215VA	220 VA	Same as predicate
Dimensions (Max.)	Width: 390 mm Height: 162 mm Depth: 502 mm	Width: 390 mm Height: 162 mm Depth: 502 mm	Width: 305 mm Height: 120 mm Depth: 370 mm	Same as predicate
Weight	13.5 kg	13.5 kg	7.4 kg	

Feature/ Technological Characteristics	Subject Device	Predicate Device	Reference Device	Substantial Equivalence Discussion
2D Observation	Available	Available	Available	Same as predicate
3D Observation	Available	Available	Available	Same as predicate
IR Observation	Available	Not Available	Available	IR Observation is an available feature in Power LED Rubina Light Source TL400, a reference device that supports this technological characteristic in the subject device. IR Observation is not a new or novel feature in endoscopic systems. The reference device is cleared for endoscopic diagnosis, treatment and video observation and includes IR capability when with compatible components of the KARL STORZ ICG Imaging System. Both the reference device and the subject device: • Are intended for use with their respective systems, • Provide/generate light for endoscopes during endoscopic procedures (diagnosis, treatment, and observation), • Use an LED for an examination light While IR Observation is not available to the end user in the predicate device, OLYMPUS CLL-S700, using a portable USB key accessory to “unlock” and activate an observation function in OLYMPUS OTV-S700 is substantially equivalent predicate device accessory, MAJ-2511. The difference in how the function is made available to the end use does not change the system indications for use, or substantially impact the technological characteristics or raise new or different questions with respect to safety and effectiveness compared to the predicate device.
Near IR Observation	Available at 2D Observation	Not Available	Available at 2D and 3D Observation	OLYMPUS OTV-S700 includes Near IR Observation at 2D and 3D observation identical to the reference device. The availability of Near IR observation is introduced with this submission and is not a change to the system indications for use and does not substantially impact the technological characteristics or raise new or different questions with respect to safety and effectiveness compared to the predicate device.
WLI Observation	Available	Available	Available	Same as predicate
NBI Observation	Available	Available	Not Available	Same as predicate

Feature/ Technological Characteristics	Subject Device	Predicate Device	Reference Device	Substantial Equivalence Discussion
HDR Observation	Available	Available	Not Available	Same as predicate
Iris Area Observation	Available	Available	Not Available	Same as predicate
Laser Mode Observation	Available	Available	Not Available	Same as predicate
Excitation Light Wavelength	Peak: 785nm wavelength band: 700 to 800nm	Peak: 785nm wavelength band: 700 to 800nm	Peak: 790nm wavelength band : 720 to 810nm	Same as predicate
Maximal Light Power Output (Power Density)	0.337W	0.337W	0.630W	Same as predicate
Front Panel (Operation)	Not Available	Not Available	Available	Same as predicate
Examination Lamp	LED	LED	LED	Same as predicate
Average Lamp Life	10,000 hours	10,000 hours	30,000 hours	Same as predicate
Emergency Lamp	LED	LED	Not Applicable	Same as predicate
Average Emergency Lamp Life	10,000 hours	10,000 hours	Not Applicable	Same as predicate
Compatible Endoscopes	Legacy 2D, 3D, and IR endoscopes	Legacy 2D and 3D endoscopes	Karl Storz 4K/2D and 4K/3D endoscopes Karl Storz 4U-LINK CCU: 4k-CH and 4K/3d-Tipcam	Substantially equivalent to the predicate device.

Summary of Non-clinical Performance Data

The VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700, VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700, and 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA are identical and unchanged from K242067.

A. Reprocessing, Sterilization and Shelf Life

This submission leverages the established reprocessing data for VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700, VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700, and 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA and adds sterilization validation of OLYMPUS CH-S700-XZ-EA with STERRAD (100S, NX, and 100NX) and V-Pro maX2.

The VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 and VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700 are not intended to be sterilized or reprocessed. Therefore, sterilization and reprocessing testing and data was not applicable for these devices. The VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 and VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700 are reusable and the associated instruction manuals for these devices includes cleaning and disinfection instructions with the following:

- Endozime AW
- 70% Isopropyl Alcohol
- Sodium Hypochlorite

The 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA is distributed non-sterile to the end user. Before using the instrument for the first time and after each use, the device must be reprocessed according to the instructions in the companion Reprocessing Manual. The 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA is validated as safe and effective for reprocessing as detailed in the Reprocessing Manual with the following:

- Manual Cleaning with Endozime AW
- Delayed Manual Cleaning with Endozime AW
- Sterilization with:
  - STERRAD 100S Short Cycle
  - STERRAD NX Standard Cycle
  - STERRAD 100NX DUO Cycle
  - V-PROmaX
  - V-PRO maX2
  - Autoclave
- Drying time of 80 minutes

The VISERA ELITE III Surgical Imaging System has a low likelihood of time-dependent product degradation. Therefore, shelf life testing and data was not applicable for the

VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700, VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700, and 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA.

B. Software Verification and Validation Testing

Software verification and validation testing of the VISERA ELITE III Surgical Imaging System has been performed and documented in compliance with the FDA guidance "Guidance for the Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

This submission leverages the established device software function documentation for OLYMPUS OTV-S700, OLYMPUS CLL-S700, and OLYMPUS CH-S700-XZ-EA from K242067 and adds documentation supporting IR observation.
This submission leverages the established device cybersecurity documentation for OLYMPUS OTV-S700, OLYMPUS CLL-S700, and OLYMPUS CH-S700-XZ-EA from K242067.

C. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC performance testing for VISERA ELITE III Surgical Imaging System is confirmed to be in compliance with the relevant requirements as noted below:

- ANSI AAMI ES 60601-1:2005+A1:2012 [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2 Edition 4.1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 4)
- IEC 60601-2-18: Edition 3.0 2009-08: Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-6 Edition 3.1: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

This submission adds the tests with IR mode to the tests in K242067.

D. Bench Testing

This submission leverages the established bench testing report for OLYMPUS OTV-S700, OLYMPUS CLL-S700, and OLYMPUS CH-S700-XZ-EA from K242067 and adds reports supporting IR observation and additional sterilization methods as follows:

- IR Performance
- Fluorescence Sensitivity
- Fluorescence Signal Uniformity
- Excitation Light Crosstalk
- Penetration Depth

- Linearity
- IR Resolution
- IR Depth of Field
- IR Photobiological Safety
- Durability

E. Risk Analysis

Risk analysis for the VISERA ELITE III Surgical Imaging System was conducted in accordance with established in-house acceptance criteria based on ISO 14971:2019. The design verification tests, and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

In the risk management process, Olympus performed preliminary analysis and evaluation to identify user tasks, user interface components, and use issues of the VISERA ELITE III Surgical Imaging System in accordance with the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices" issued on February 2, 2016.

Olympus determined that human factors validation testing was not required for the addition of IR mode to the VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 and VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700. For 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA, user tasks associated with reprocessing procedures for Sterrad sterilization were identified as critical tasks. Therefore, Olympus performed human factors validation and determined that risks have been mitigated effectively.

Summary of Clinical Performance Data

No clinical data were collected.

Conclusion

Based on the results of the comparison of the indications for use, technological characteristics, and performance testing of the subject and predicate device, the change does raise no new issues of safety and effectiveness. The device is substantially equivalent to the predicate device and is as safe, as effective, and performs as well as or better than the predicate device.