April 2, 2025

Olympus Corporations of the Americas
Elizabeth Greene
Program Manager
800 West Park Drive
Westborough, Massachusetts 01581

Re: K242067
Trade/Device Name: Visera Elite III Video System Center Olympus Otv-s700; Visera Elite III Led Light Source Olympus Cll-s700; 4k Camera Head Olympus Ch-s700-xz-ea
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FET, NWB
Dated: March 4, 2025
Received: March 4, 2025

Dear Elizabeth Greene:

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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.04.02 22:57:33 -04'00'

Tanisha Hithe
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)*
K242067

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

Indications for Use *(Describe)*
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

For

VISERA ELITE III Surgical Imaging System

General Information

Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Phone: (+81) 42-642-2111 Fax: (+81) 42-642-2307 Establishment Registration Number: 8010047
Manufacturer:	Shirakawa Olympus Co., Ltd. 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan
510(k) Submitter:	Olympus Corporation of the Americas 800 West Park Drive Westborough, MA 01581
Establishment Registration Number:	2429304
Contact Person:	Elizabeth Greene Program Manager Mobile: (772) 254-3793 Email: elizabeth.greene@olympus.com
Date Prepared:	July 12, 2024

Device Description

Device Name:	VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700
Model Name:	OLYMPUS OTV-S700
Generic/Common Name:	Endoscopic Video Imaging System
Regulation Number:	876.1500
Regulatory Class:	Class II
Classification Name:	Endoscope and accessories
Product Codes:	FET, NWB
Review Panel:	Gastroenterology/Urology

Device Name:	VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700
Model Name:	OLYMPUS CLL-S700
Generic/Common Name:	Endoscopic Video Imaging System
Regulation Number:	876.1500
Regulatory Class:	Class II
Classification Name:	Endoscope and accessories
Product Codes:	FET, NWB
Review Panel:	Gastroenterology/Urology

Device Name:	4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA
Model Name:	OLYMPUS CH-S700-XZ-EA
Generic/Common Name:	Endoscopic Video Imaging System
Regulation Number:	876.1500
Regulatory Class:	Class II
Classification Name:	Endoscope and accessories
Product Codes:	FET, NWB
Review Panel:	Gastroenterology/Urology

Predicate Device

Device Name	510(k) Submitter	510(k) No.
OLYMPUS OTV-S300 Video System Center w/ Light Source	Olympus Medical Systems Corp.	K201200
OLYMPUS CH-S200-XZ-EA HD 3CMOS AUTOCLAVABLE CAMERA HEAD	Olympus Medical Systems Corp.	K190449

Indications for Use

Table 1 details the Indications for Use for the devices in the VISERA ELITE III Surgical Imaging System.

Table 1. Indications for Use for VISERA ELITE III Surgical Imaging System

Device	Indications for Use
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.

Device	Indications for Use
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.

Device Description

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 devices of the VISERA ELITE III Surgical Imaging System are the subject of this premarket notification submission:

- **VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 (Model: OLYMPUS OTV-S700)** - 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.
    - **VISERA ELITE III 3D Upgrade Pack (Model: MAJ-2511)** - A function activation portable memory key accessory that unlocks the 3D software function when connected with OTV-S700 to enable the observation of 3D mode.
- **VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700 (Model: OLYMPUS CLL-S700)** - A LED light source provides examination light to a video endoscope and a camera head.
- **4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA (Model: 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.

Comparison of Technological Characteristics

Table 2 compares VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 to the predicate device with respect to intended use, and technological characteristics, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 2. Comparison of the VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 to the predicate device

Feature/Technological Characteristics	Subject Device	Predicate Device
Regulatory		
Device Name	VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700	VISERA ELITE II Video System Center w/Light Source
Model Number	OLYMPUS OTV-S700	OLYMPUS OTV-S300
Legal Manufacturer	Same as the predicate	OLYMPUS MEDICAL SYSTEMS CORP.
Regulatory Decision	This submission	K201200
Regulation Number	Same as predicate	876.1500

Feature/Technological Characteristics	Subject Device	Predicate Device
Regulation Name	Same as predicate	Endoscope and accessories
Product Code	Same as predicate	FET, NWB
Regulatory Class	Same as predicate	II
Classification Panel	Gastroenterology/Urology	Obstetrics/Gynecology
Indications for Use	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.	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.
Specifications		
Main Function	Video System Center	Video System Center and Light Source
Rated Voltage	AC 100-240V/ 50-60Hz	AC 100V/ 50-60Hz
Rated Input	<170VA	400VA
Dimensions (Max.)	W: 390 x H: 198 x D: 500 mm	W: 383 x H: 199 x D: 506 mm
Weight	12.1 kg	19.3 kg
2D Observation	Same as predicate	Available
3D Observation	With the accessory MAJ-2511	Available
WLI Observation	Same as predicate	Available
NBI Observation	Same as predicate	Available
HDR Observation	Available	Not Available
Iris Area Observation	Same as predicate	Available
Laser Mode Observation	Same as predicate	Available
Automatic Gain Control	Same as predicate	Available
Front Panel (Operation)	Same as predicate	Touch Panel
Fog Free Function	Same as predicate	Available
Compatible Endoscopes	Same as predicate	Legacy 2D and 3D endoscopes

Table 3 compares VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700 to the predicate device with respect to intended use, technological characteristics, and principle of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 3. Comparison of the VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700 to the predicate device

Feature/Technological Characteristics	Subject Device	Predicate Device
Regulatory		
Device Name	VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700	VISERA ELITE II Video System Center w/Light Source
Model Number	OLYMPUS CLL-S700	OLYMPUS OTV-S300
Legal Manufacturer	Same as the predicate	OLYMPUS MEDICAL SYSTEMS CORP.
Regulatory Decision	This submission	K201200
Regulation Number	Same as predicate	876.1500
Regulation Name	Same as predicate	Endoscope and accessories
Product Code	Same as predicate	FET, NWB
Regulatory Class	Same as predicate	II
Classification Panel	Gastroenterology/Urology	Obstetrics/Gynecology
Indications for Use	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.	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.
Specifications		
Main Function	Light Source	Video System Center and Light Source
Rated Voltage	AC 100-240V/ 50-60Hz	AC 100V/ 50-60Hz
Rated Input	215VA	400VA
Dimensions (Max.)	W: 390 x H: 162 x D: 502 mm	W: 383 x H: 199 x D: 506 mm
Weight	13.5 kg	19.3 kg
2D Observation	Same as predicate	Available
3D Observation	Same as predicate	Available
WLI Observation	Same as predicate	Available
NBI Observation	Same as predicate	Available
Iris Area Observation	Same as predicate	Available
Laser Mode Observation	Same as predicate	Available
Front Panel (Operation)	Not Available	Touch Panel
Examination Lamp	Same as predicate	LED
Average Lamp Life	Same as predicate	10,000 hours
Emergency Lamp	Same as predicate	LED
Average Emergency Lamp Life	Same as predicate	10,000 hours
Compatible Endoscopes	Same as predicate	Legacy 2D and 3D endoscopes

Table 4 compares 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA to the predicate device with respect to intended use, technological characteristics, and principle of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 4. Comparison of the 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA to the predicate device

Feature/Technological Characteristics	Subject Device	Predicate Device
Regulatory		
Device (Model) Name	4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA	HD 3CMOS AUTOCLAVABLE CAMERA HEAD
Model Number	OLYMPUS CH-S700-XZ-EA	OLYMPUS CH-S200-XZ-EA
Legal Manufacturer	Same as the predicate	OLYMPUS MEDICAL SYSTEMS CORP.
Regulatory Decision	This submission	K190449
Regulation Number	Same as predicate	876.1500
Regulation Name	Same as predicate	Endoscope and accessories
Product Code	Same as predicate	FET, NWB
Regulatory Class	Same as predicate	II
Classification Panel	Same as predicate	Gastroenterology/Urology
Indications for Use	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.	The camera head has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and observation.
Specifications		
Observation Function	Same as predicate	2D Function
4K Compatible	Available	Not Available
Head Dimensions (Max.)	W: 44 x H: 54 x L:133 mm	W: 44 x H: 52 x L: 120 mm
Cable	Diameter: 5.1 mm x L: 3 m	Diameter: 6.8 mm x L: 3 m
Connector Surface	Card edge Connector with Optical Connection	Card Edge Connector
Image Module	1 CMOS	3CMOS
Pixel Count	4,152(H) x 3,062(V) = 12,713,424 pixels	1,944(H) x 1,092(V) = 2,122,848 pixels (Per CMOS)
Pixel Size	1.55µm(H) x 1.55µm(V)	2.75µm(H) x 2.75µm(V)
Focus Control	Electrical manual focus with focus control switches	Electrical manual focus with focus control switches
	Electrical automatically focus with one-touch auto focus/Continuous auto focus switch	Not Available
	Continuous electrical automatically focus	Not Available
Optics Zoom	Not Available	Available
Field of View	20.7° 88° with representative rigid scope	10.90° (Low magnification) to 22.42° (High magnification)

Feature/Technological Characteristics	Subject Device	Predicate Device
NBI Observation	Same as predicate	Available
Image Signal Transmission	Optical transmission (Digital)	Electro transmission (Digital)
Degree of protection against electric shock	Type CF	Type BF
Number of remote switches	Same as predicate	3
Compatible endoscopes	Same as predicate	Legacy 2D endoscopes
Head Weight	270 g (excluding cable)	295 g (excluding cable)
Reprocessing	End User Sterilized Autoclaving/V-PRO	End User Sterilized Autoclaving/V-PRO/STERRAD

Compliance to Voluntary Standards

The following voluntary standards have been applied to the subject devices:

- ISO 15223-1
- ISO 7000
- ISO 7010
- ANSI AAMI ST98:2022
- ISO 17664-2 First Ed. 2021-02
- ISO 17665-1 First Ed. 2006-08
- ANSI AAMI IEC 62304:2006/A1: 2016
- IEC 81001-5-1 Ed. 1.0 2021-12
- AAMI TIR57:2016
- ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012
- IEC 60601-1-2 Ed. 4.1 2020-09
- IEC 60601-1-6 Ed. 3.2 2020-07
- IEC 60601-4-2 Ed. 1.0 2016-05
- IEC 60601-2-18 Ed. 3.0 2009-08
- ISO 8600-1:2015
- ISO 8600-3:2019
- IEC 62471:2006-07
- IEC 60825-1 Edition 2.0 2007-03
- ISO 14971:2019

Summary of Performance Testing

The following performance testing was conducted in support of the substantial equivalence determination.

Reprocessing, Sterilization, and Shelf Life Validation

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:
    - V-PRO maX
    - 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.

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.”

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

Bench Testing

Bench testing as listed below was conducted for VISERA ELITE III Surgical Imaging System to ensure that the subject device performs as intended and meets design specifications for the following:

- Field of View and Direction of View
- Resolution
- Image Noise and Dynamic Range
- Brightness
- Image Intensity Uniformity
- Color Performance
- Latency
- Iris Area
- Laser Mode
- Magnification
- Distortion
- Depth of Field
- Photobiological Safety
- Laser Product Safety
- Auto Focus Function
- High Dynamic Range (HDR) Function
- Durability

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 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 were identified as critical tasks. Therefore, Olympus performed human factors validation and determined that risks have been mitigated effectively.

Animal and Clinical Testing

Animal and Clinical testing was not applicable and not performed.

Substantial Equivalence

Olympus has determined that the VISERA ELITE III Surgical Imaging System is substantially equivalent to the legally marketed predicate devices, VISERA ELITE II Video System Center OLYMPUS OTV-S300 (K201200) and the VISERA ELITE II HD 3CMOS Autoclavable Camera Head OLYMPUS CH-S200-XZ-EA (K190449) for the following reasons:

- same intended use;
- technological characteristics (design, materials, and operations) are similar or identical to the predicate devices; and
- does not introduce any new or novel treatments or standard of care that differs from predicate devices in commercial use.

VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700

The intended use, principles of operation, fundamental technology of VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 are identical to the predicate device. The differences in specifications include separation of processing and light source functions, rated voltage and input, device dimensions, and weight. New features include HDR Observation and 3D functionality availability via the accessory, MAJ-2511 which have been verified as safe and effective. The difference in indications for use between the VISERA ELITE III VIDEO SYSTEM CENTER OLYMPUS OTV-S700 and the VISERA ELITE II Video System Center with Light Source is not a change from single use labeling to reusable and is 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 these differences did not identify any new risks or significantly modified existing risks or raise new or different questions with respect to safety and effectiveness.

VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700

The intended use, principles of operation, fundamental technology of VISERA ELITE III LED LIGHT SOURCE OLYMPUS CLL-S700 are identical to the predicate device. The differences in specifications include rated voltage and input, device dimensions, weight, and absence of a front panel. The difference in indications for use between the VISERA ELITE III LED LIGHT

SOURCE OLYMPUS CLL-S700 and the VISERA ELITE II Video System Center with Light Source is not a change from single use labeling to reusable, is 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 these differences did not identify any new risks or significantly modified existing risks or raise new or different questions with respect to safety and effectiveness.

4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA

The intended use, principles of operation, fundamental technology of 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA are identical to the predicate device. The differences in specifications include 4K compatibility, device dimensions, image module, increased pixel count, decreased pixel size, additional focus control, digital zoom, increased field of view, image signal transmission, degree of protection against electric shock, and weight. The difference in indications for use between the 4K CAMERA HEAD OLYMPUS CH-S700-XZ-EA and the HD 3CMOS AUTOCLAVABLE CAMERA HEAD is not a change from single use labeling to reusable, is 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 these differences did not identify any new risks or significantly modified existing risks or raise new or different questions with respect to safety and effectiveness.

The VISERA ELITE III Surgical Imaging System has been verified and validated to be equivalent in electrical performance for use with video endoscopes/camera head to output image signals to a monitor for endoscopic diagnosis, treatment, and observation when compared to the predicates. As the electrical safety and electromagnetic compatibility test results demonstrate equivalent performance, Olympus has determined there are no new concerns or modified existing risks regarding safety and effectiveness of the subject device.

Conclusion

In summary, the VISERA ELITE III Surgical Imaging System (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) is substantially equivalent to the predicate devices and raises no new questions of safety or effectiveness.