March 9, 2022

Olympus Medical Systems Corp.
% Elizabeth Greene
Program Manager
Olympus Corporation of the Americas
3500 Corporate Parkway
Center Valley, Pennsylvania 18034-0610

Re: K220069
Trade/Device Name: 4K UHD LCD Monitor, Model Number: OEV321UH
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 28, 2021
Received: January 10, 2022

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220069

Device Name
4K UHD LCD Monitor, Model Number: OEV321UH

Indications for Use *(Describe)*
The 4K UHD LCD Monitor is intended to provide 4K 2D color video displays of images from endoscopic/laparoscopic camera systems and other compatible medical imaging systems. The 4K UHD LCD Monitor is a wide-screen, high-definition, medical grade monitor for real-time use during endoscopic/laparoscopic procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments.

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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510(k) Summary

For

4K UHD LCD MONITOR, Model Number: OEV321UH

General Information

Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Phone: (+81) 42-642-2694 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 Phone: (+81) 248-27-2239 Fax: (+81) 248-27-2429 Establishment Registration Number: 3002808148 Sony Global Manufacturing & Operations Corporation Kosai Site 554 Sakaijuku, Kosai-shi, Sizuoka 431-0496, Japan Phone: +(1) 201-358-4945 Establishment Registration Number: 3004421482
510(k) Submitter:	Olympus Corporation of the Americas 3500 Corporate Parkway Center Valley, PA 18034-0610
Establishment Registration Number:	2429304
Contact Person:	Elizabeth Greene Program Manager Fax: 484-896-7128 Mobile: (561) 774-1483 Email: elizabeth.greene@olymus.com
Date Prepared:	December 28, 2021

Device Description

Device Name:	4K UHD LCD Monitor
Model Name:	OEV321UH
Generic/Common Name:	LCD Monitor
Regulation Number:	876.1500
Regulatory Class:	Class II
Classification Name:	Endoscope and accessories
Product Codes:	GCJ
Review Panel:	General and Plastic Surgery

Predicate Device

Device Name	510(k) Submitter	510(k) No.
Sony LMD-X310S LCD Monitor	Sony Electronics Incorporated	K150377

Indications for Use

The 4K UHD LCD Monitor is intended to provide 4K 2D color video displays of images from endoscopic/laparoscopic camera systems and other compatible medical imaging systems. The 4K UHD LCD Monitor is a wide-screen, high-definition, medical grade monitor for real-time use during endoscopic/laparoscopic procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments.

Principle of Operation

This monitor displays color video images that are output from medical imaging systems on the LCD (liquid crystal display) panel.

Liquid crystal and color filters are laid on the front of the flat light source (backlight) of the LCD panel. The LCD panel displays images by controlling the aperture of the liquid crystal according to input signals.

Comparison of Technological Characteristics

Table 5-1 compares 4K UHD LCD Monitor OEV321UH 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 5-1: Comparison of the technological characteristics of 4K UHD LCD Monitor to predicate device

Feature/Technological Characteristics	Subject Device	Predicate Device
Regulatory		
Device Name **Model Number**	Olympus 4K UHD LCD Monitor OEV321UH	Sony LCD Monitor LMD-X310S

Feature/Technological Characteristics	Subject Device	Predicate Device
Regulatory Decision	This submission	K150377
Product Code	Same as predicate	GCJ
Regulatory Class	Same as predicate	II
Regulation Number	Same as predicate	876.1500
Regulation Name	Same as predicate	Endoscope and accessories
Classification Panel	Same as predicate	General and Plastic Surgery
Indications for Use	The 4K UHD LCD Monitor is intended to provide 4K 2D color video displays of images from endoscopic/laparoscopic camera systems and other compatible medical imaging systems. The 4K UHD LCD Monitor is a wide-screen, high-definition, medical grade monitor for real-time use during endoscopic/laparoscopic procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments.	The LCD Monitor is intended to provide 4K 2D color video displays of images from endoscopic/laparoscopic camera systems and other compatible medical imaging systems. The LCD Monitor is a wide-screen, high-definition, medical grade monitor for real-time use during minimally invasive surgical procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices, and similar medical environments.
Mode of Action	Same as predicate	This monitor displays color video images that are output from medical imaging systems on the LCD (liquid crystal display) panel. Liquid crystal and color filters are laid on the front of the flat light source (backlight) of the LCD panel. The LCD panel displays images by controlling the aperture of the liquid crystal according to input signals.
Intended Environment	Same as predicate	Hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments
Intended Users	Same as predicate	Doctors and Assistants
System Parameters and Specifications		
Power	Same as predicate	AC 100-240V/ 50-60Hz
Dimensions (excluding max. protrusions)	753.9 × 476.3 × 79.2mm	753.8 × 456.4 × 69.3mm
Display Dimension	Same as predicate	2D
Input Signals	12G-SDI1, 12G-SDI2, 3G-SDI, DisplayPort, HDMI, DVI-D, DC IN	DVI-D, HDMI, 3G/HD/SD-SDI
Output Signals	12G-SDI1, 12G-SDI2, 3G-SDI, CloneOUT, +5V DC OUT, +12V DC OUT	DVI-D, 3G/HD/SD-SDI
Display Device	Same as predicate	LCD panel (IPS)
Backlight Device	Same as Predicate	LED

Feature/Technological Characteristics	Subject Device	Predicate Device
Viewing Angle	Same as predicate	Right>89[deg] (CR>10) Left>89[deg] (CR>10) Up>89[deg] (CR>10) Down>89[deg] (CR>10)
Active Screen Size	697(H)×392(V) mm	697.958(H)×368.064(V) mm
Resolution	3840 × 2160 pixels	4096 × 2160 pixels
Luminance	≥280[cd/m^2]	≥550[cd/m^2]
Primary Colors	Same as predicate	RGB
Gamma Curve	1.8, 2.0, 2.2, 2.4, 2.6, DICOM, Endoscope, HLG	1.8, 2.0, 2.2, 2.4, 2.6, DICOM, Endoscope, Highlight
Color Space	Same as predicate	Auto, BT.709, BT.2020, Native
Refresh Rate	Same as predicate	50/60Hz
Frame Rate	Same as predicate	50/60 fps
Display Format	Same as predicate	Normal Multi display Flip display

Compliance to Voluntary Standards

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

- ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012
- IEC 60601-1-2: 2014
- ISO 14971:2007/2019

Summary of Performance Testing

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

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC performance testing for the 4K UHD LCD Monitor OEV321UH is confirmed to be in compliance with the relevant requirements as noted below.

- ANSI AAMI ES 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 4)

Software Verification and Validation Testing

Software testing has been performed and documented in compliance with the FDA guidance "Guidance for the Content of Premarket Submissions for Software contained in medical devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."

Risk Analysis
Risk analysis for the subject device was conducted in accordance with established in-house acceptance criteria based on ISO 14971. 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, the human factors validation testing was also performed in accordance with the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices". In terms of human factors, an assessment of applicable adverse events along with a review of the overall risk analysis was conducted. These assessments confirmed that there was no unacceptable user-related residual risk for the 4K UHD LCD Monitor OEV321UH.

Animal and Clinical Testing
Animal and Clinical testing was not applicable and not performed.

Substantial Equivalence
Olympus has determined that the 4K UHD LCD Monitor OEV321UH is substantially equivalent to the legally marketed predicate device, Sony LCD Monitor LMD-X310S (K150377) 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.

The intended use, principles of operation, fundamental technology of the 4K UHD LCD Monitor OEV321UH are identical to the predicate device. The differences in system parameters, and specifications include device dimensions, input and output signals, active screen size, resolution, luminance, and gamma curve. The 4K UHD LCD Monitor OEV321UH is a general use medical monitor and is not intended to be used in limited procedures. The difference in indications for use between the 4K UHD LCD Monitor OEV321UH and Sony LCD Monitor LMD-X310S 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 4K UHD LCD Monitor OEV321UH has been verified and validated to be equivalent in electrical performance for displaying images from endoscopic/laparoscopic camera systems and other compatible medical imaging systems, when compared to the predicate. As the electrical safety and electromagnetic compatibility test results demonstrate equivalent performance, Olympus believe there are no new concerns or modified existing risks regarding safety and effectiveness of the subject device.

Conclusion

In summary, the Olympus 4K UHD LCD Monitor OEV321UH is substantially equivalent to the predicate device and raise no new questions of safety or effectiveness.