August 26, 2026

Sony Corporation
Hideaki Kawano
Official Correspondent
5-1-1, Minatomirai
Nishi-Ku
Yokohama-Shi, Kanagawa 220-8750
Japan

Re: K260972
Trade/Device Name: OEV-271MUH LCD Monitor;OEV-321MUH LCD Monitor;OEV-431MUH LCD Monitor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 25, 2026
Received: August 25, 2026

Dear Hideaki Kawano:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.08.26 15:06:03 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260972

Please provide the device trade name(s).

OEV-271MUH LCD Monitor;
OEV-321MUH LCD Monitor;
OEV-431MUH LCD Monitor

Please provide your Indications for Use below.

The LCD Monitor is intended to provide 4K 2D color video displays of images from endoscopic/laparoscopic camera systems, surgical microscope and other compatible medical imaging systems.
The LCD Monitor is a widescreen, 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

510(k) #: K260972

510(k) Summary

Prepared on: 2026-08-25

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Sony Corporation
Applicant Address	5-1-1, Minatomirai Nishi-ku Yokohama-shi Kanagawa 220-8750 Japan
Applicant Contact Telephone	NA
Applicant Contact	Mr. Hideaki Kawano
Applicant Contact Email	Hideaki.Kawano@sony.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OEV-271MUH LCD Monitor; OEV-321MUH LCD Monitor; OEV-431MUH LCD Monitor
Common Name	Endoscope and accessories
Classification Name	Laparoscope, General & Plastic Surgery
Regulation Number	876.1500
Product Code(s)	GCJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K150377	Sony LMD-X310S LCD Monitor	GCJ

Device Description Summary

21 CFR 807.92(a)(4)

This monitor displays color video images that are output from medical imaging systems on the LCD panel.
LCD panel consists of liquid crystal, color filters, and LED backlights.
The panel displays images by controlling the liquid crystal and backlights according to input signals.

Features
- Compliance with medical safety standards in the U.S.A.
- High brightness/high-resolution 4K panel
- Control panel
- Flat surface for better maintenance

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The LCD Monitor is intended to provide 4K 2D color video displays of images from endoscopic/laparoscopic camera systems, surgical microscope and other compatible medical imaging systems.
The LCD Monitor is a widescreen, 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

An additional example of a medical imaging system has been included; however, the Indications for Use are substantial equivalent.

Technological Comparison

21 CFR 807.92(a)(6)

As a result of comparison with the predicate device, the following differences are confirmed:
- Dimensions
- Input signals
- Output signals
- Backlight
- Efficient picture size
- Maximum Luminance

The subject devices have been validated in accordance with IEC 62304, and there is no associated risk. Thus, these differences do not affect safety and effectiveness.
Therefore, the subject devices are substantially equivalent to the predicate device regarding technological characteristics.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following applied standards support the substantial equivalence determination.
- IEC 60601-1
- IEC 60601-1-2
- IEC 62304

Not Applicable

Based on the information provided in this premarket notification, the subject device has been proven to be as safe and effective as the predicate device. Therefore, we have concluded that the predicate device and the subject device are substantially equivalent.