Jvckenwood Corporation
Takayuki Kasahara
Manager
3-12 Moriya-cho, Kanagawa-ku, Yokohama-shi
Yokohama, Kanagawa 221-0022
Japan

August 1, 2024

Re: K241105
Trade/Device Name: 3MP Color LCD Monitor (CL-S301)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: July 5, 2024
Received: July 5, 2024

Dear Takayuki Kasahara:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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

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

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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.

Submission Number *(if known)*

K241105

Device Name

3MP Color LCD Monitor (CL-S301)

Indications for Use *(Describe)*

CL-S301 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel.
It is not meant to be used in digital mammography.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Submitted Information:	JVCKENWOOD Corporation 3-12, Moriya-cho, Kanagawa-ku, Yokohama-shi, Kanagawa, 221-0022 Japan
Contact Person:	Takayuki Kasahara, Manager Email: kasahara.takayuki@jvckenwood.com Tel: +81-45-450-2715 Fax: +81-45-450-1926
Date Prepared:	August 1, 2024
Device Name:	3MP Color LCD Monitor CL-S301
Common Name:	display, diagnostic radiology
Classification Name:	Class II (Part 892 Radiology Devices Sec. 892.2050 Medical Image Management and Processing System
Product Code:	PGY
Predicate Device:	21.3 inch Color LCD Monitor CL-S300 (CL-S300 / K173434)
Device Description:	21.3 inch Color LCD Monitor 1536 x 2048 (portrait) ■ High-luminance color LCD panel, which has wide view angle, is used for this product. It is designed for medical image display. ■ Luminance stabilization function composed with luminance sensor and luminance control circuit always observes the luminance and makes it stable. ■ Images are faithfully displayed along grayscale characteristics (DICOM GSDF) based on the calibrated data stored to the lookup table of the monitor. ■ Luminance and the color mura correction functions will help achieve uniformity on the whole screen.

Intended Use:	CL-S301 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It is not meant to be used in digital mammography.
Cybersecurity:	FDA guidance located at https://www.fda.gov/media/119933/download, is followed for cybersecurity concerns.
Substantial Equivalence:	CL-S301 shares the same technical characteristics, application, and intended use as our predicate device CL-S300. (CL-S300 / K173434)

JVCKENWOOD Corporation
3-12, Moriya-cho, Kanagawa-ku, Yokohama-shi, Kanagawa, 221-0022, Japan
Tel +81-45-450-2715

JVCKENWOOD

Device Description & Substantial Equivalence Comparison

	Predicate device LCD Monitor CL-S300	Proposed device LCD Monitor CL-S301	Explanation of Differences
510(k) Number	**K173434**	**K241105**	—
Indication for use	CL-S300 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It is not meant to be used in digital mammography	CL-S301 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It is not meant to be used in digital mammography.	—
Display Technology	IPS LCD panel with TFT active-matrix array with LED backlight	IPS LCD panel with TFT active-matrix array with LED backlight	—
Screen size	Diagonal: 21.3 Aspect ratio: 4:3	Diagonal: 21.3 Aspect ratio: 4:3	—
Backlight type	LED	LED	—
Frame rate and refresh rate	60Hz	60Hz	—
Resolution / Pixel array	3MP (2048 x 1536)	3MP (2048 × 1536)	—
Pixel Pitch	Horizontal: 0.2115 mm Vertical: 0.2115 mm	Horizontal: 0.2115 mm Vertical: 0.2115 mm	—
Subpixel pattern	Stripe RGB	Stripe RGB	—
Pixel aperture ratio	38.7%	57.1%	The diagnostic performance is equivalent to that of the predicate devices, though the aperture ratio is higher.
Subpixel driving (spatial and temporal dithering)	N/A	N/A	—
Display Interface	Input: DVI-D x1 DisplayPort x1 Output: DisplayPort x1	Input: DisplayPort x2 USB-C x1 Output: DisplayPort x1	The proposed device is not equipped with a DVI-D input, but this is not a problem since graphics cards are no longer equipped with a DIV-D output.
Video bandwidth	Dot clock: 216 MHz	Dot clock: 216 MHz	—

	Predicate device LCD Monitor CL-S300	Proposed device LCD Monitor CL-S301	Explanation of Differences
User controls	DICOM CONFORMANCE TEST CONFIGURATION INPUT SOURCE DYNAMIC GAMMA AUTO TEXT MODE FUNCTON EDID TEST PATTERN FACTORY PRESET USB POWER INPUT SOURCE AUTO SCANNING HUMAN SENSOR DISPLAYPORT	DICOM CONFORMANCE TEST CONFIGURATION INPUT SOURCE DYNAMIC GAMMA AUTO TEXT MODE FUNCTION EDID TEST PATTERN FACTORY PRESET USB POWER MULTI PIXEL ENHANCER TURBO LUMINANCE COLOR MODE USB UP-PORT INPUT SELECT USB-C DATA SETTING SELF CALIBRATION RESULT DISPLYPORT VERSION RECOMMENDED REPLACE TIMING VISUAL POINT MODE	The performance of the proposed device is the same as the predicate device, though some user controls were added or removed.
Ambient light sensing	Built-in Sensor (For correction during calibration)	Built-in Sensor (For correction during calibration)	—
Touch-screen technology	N/A	N/A	—
Luminance calibration tools / Quality-control procedures	Hardware: Integrated sensor External sensor Software: QA Medivisor / Medivisor NX FCAL	Hardware: Integrated sensor External sensor Software: QA Medivisor Agent	—
Additional Software/Firmware	N/A	N/A	—

Physical Laboratory Tests

Performance test items in the guidance	Test method(s)
a. Spatial resolution	The bar pattern is displayed and captured by a digital camera equipped with a macro lens. The MTF is calculated with the captured data.
b. Pixel defects (maximum counts, allowed defect types, and locations)	ISO 13406-2 IDMS 1.03, 7.6 DEFECTIVE PIXELS Pixel defects are counted based on the ISO13406-2, 3.4.13 table 3.
c. Artifacts	AAPM-TG18, 4.9 Miscellaneous Tests IDMS 1.03, 4.6 ARTIFACTS & IRREGULARITIES
d. Temporal response	IDMS 1.03, 10.2.3 GRAY-TO-GRAY RESPONSE TIME Rise and fall time constants at four grayscale intervals (0-100%, 5-95%, 10-90%, 40-60%) are provided by the panel manufacturer.
e. Luminance (maximum, minimum, achievable, and recommended)	L_{min} and L_{max} on the calibrated luminance are confirmed.
f. Conformance to a grayscale-to-luminance function (e.g., DICOM GSDF)	AAPM-TG18, 4.3.5 Advanced Luminance Response Luminance response for 256 levels are measured.
(For mammography displays) g. Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and four corners	N/A
(For mammography displays) h. Luminance uniformity or Mura test	N/A
(For mammography displays) i. Stability of luminance and chromaticity response with temperature and time of operation or on-time	N/A
(For mammography displays) j. Spatial noise	N/A
(For mammography displays) k. Reflection coefficient	N/A
(For mammography displays) l. Veiling glare or small-spot contrast	N/A
(For color displays) m. Color tracking (primary colors and color gamut)	Color scale: IDMS 1.03, 6. Gray- and Color-Scale Measurement IDMS 1.03, 5.4 Color-Signal White Color gamut volume: IDMS 1.03, 5.31 Volume-Color-Reproduction Capability
(For color displays) n. Gray tracking (gray shades and white point)	AAPM-TG196 Gray Tracking IEC 62563-1: 2009 + AMD1: 2016 CSV, 7.4.9 Greyscale chromaticity evaluation

Conclusion

As shown above, the intended use of the subject and predicate devices are identical, the technical characteristics are similar, and any differences between the characteristics do not affect the device safety or effectiveness. The results of the performance testing and the verification and validation demonstrate that the subject device is substantially equivalent to the currently marketed predicate device.