JVCKENWOOD Corporation
% Hideki Tengeiji
Senior Manager
3-12, Moriya-cho, Kanagawa-ku
Yokohama-shi, Kanagawa 221-0022
JAPAN

June 29, 2021

Re: K203733
Trade/Device Name: 12MP Color Digital Mammography LCD Monitor CL-S1200
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: PGY
Dated: May 21, 2021
Received: May 26, 2021

Dear Hideki Tengeiji:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203733

Device Name
12MP Color Digital Mammography LCD Monitor CL-S1200

Indications for Use *(Describe)*
CL-S1200 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It's intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

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

Submitted Information:	JVCKENWOOD Corporation 3-12, Moriya-cho, Kanagawa-ku, Yokohama-shi, Kanagawa, 221-0022 Japan
Contact Person:	Hideki Tengeiji, Senior Manager Email: tengeiji.hideki@jvckenwood.com Tel: +81-45-450-2715 Fax: +81-45-450-1926
Date Prepared:	May 21, 2021
Device Name:	12MP Color Digital Mammography LCD Monitor CL-S1200
Common Name:	display, diagnostic radiology
Classification Name:	Class II (Part 892 Radiology Devices Sec. 892.2050 Medical Image Management and Processing System)
Predicate Device:	21.3 inch (54cm) Color LCD Monitor CL-S500 (CL-S500/ K191137)
Device Description:	30.9 inch Color Digital Mammography LCD Monitor 4200 x 2800 (landscape) ■ High-luminance color LCD panel, which has wide view angle, is used for this product. It is designed for medical image display including mammography. ■ 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. ■A glass filter protects the surface of the LCD panel.

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Cybersecurity:	FDA guidance located at https://www.fda.gov/media/86174/download, are followed for cybersecurity concerns.
Intended Use:	CL-S1200 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It's intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.
Substantial Equivalence:	CL-S1200 shares the same technical characteristics, application, and intended use as our predicate device CL-S500/ K191137.

JVCKENWOOD Corporation
Healthcare Business Division
3-12, Moriya-cho, Kanagawa-ku,
Yokohama-shi, Kanagawa, 221-0022 Japan

Device Description & Substantial Equivalence Comparison

	Predicate device LCD Monitor CL-S500	Proposed device LCD Monitor CL-S1200	Explanation of Differences
510(k) Number	K191137	-	—
Indication for use	CL-S500 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. They're intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.	CL-S1200 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It's intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.	—
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" (54.1cm) Aspect ratio: 4:5	Diagonal: 30.9" (78.4cm) Aspect ratio: 3:2	Half of the screen size of the proposed device is the same as the predicate device.
Backlight type	LED	LED	—
Frame rate and refresh rate	Portrait: Horizontal: 129.1KHz Vertical: 50Hz Landscape: Horizontal: 103.5KHz Vertical: 50Hz	Landscape: Horizontal: 170.5 kHz Vertical: 60 Hz	Although refresh rate of the proposed device is higher than the predicate device, the difference is not distinguishable when observing still images.
Resolution / Pixel array	5MP (2048 x 2560)	12MP (4200 x 2800)	Less than half of the resolution of the proposed device is the same as the predicate device.
Pixel Pitch	Horizontal: 0.165mm Vertical: 0.165mm	Horizontal: 0.1554mm Vertical: 0.1554mm	Pixel pitch of the proposed device is equal to smaller than that of the predicated device.
Subpixel pattern	Stripe RGB	Stripe RGB	—
Pixel aperture ratio	53.00%	56.50%	Almost the same.
Subpixel driving (spatial and temporal dithering)	N/A	N/A	—
Display Interface	Input: DVI-D x1 DisplayPort x1 Output: DisplayPort x1	Input: DisplayPort x2 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: 285 MHz	Dot clock: 746 MHz	Since the resolution and refresh rate are higher than the predicate device, the dot clock of the proposed device is higher.

User controls	Input signal switch Dynamic gamma AUTO TEXT Configuration switch, DisplayPort Power, USB Power	Input signal switch Dynamic gamma AUTO TEXT EDID switch Configuration switch DisplayPort Power USB Power Pixel Enhancer Turbo Luminance Dynamic Range Extension Auto Config Select	The functions in the predicate device are also available in the proposed device.
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 FCAL	—
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	AAPM-TG18, 4.4 Luminance Spatial and Angular Dependencies
(For mammography displays) h. Luminance uniformity or Mura test	AAPM-TG18, 4.4 Luminance Spatial and Angular Dependencies
(For mammography displays) i. Stability of luminance and chromaticity response with temperature and time of operation or on-time	Temperature: Luminance and chromaticity response in 0 °C, 20 °C, 25 °C, 30 °C, and 40 °C Time: Luminance and chromaticity are measured after the AC power of the display is turned on.
(For mammography displays) j. Spatial noise	The uniform area including the two lines is displayed and captured by a digital camera equipped with a macro lens. The noise power spectrum is calculated with the captured data.
(For mammography displays) k. Reflection coefficient	AAPM-TG18, 4.2 Display Reflection Specular and Diffuse reflection coefficients are measured.
(For mammography displays) l. Veiling glare or small-spot contrast	AAPM-TG18, 4.7 Veiling Glare
(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.