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

December 21, 2022

Re: K222864
Trade/Device Name: 8MP Color LCD Monitor CL-R813
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: December 14, 2022
Received: December 15, 2022

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 and Part 809); 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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222864

Device Name
8MP Color LCD Monitor CL-R813

Indications for Use *(Describe)*
CL-R813 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.

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510(k) SUMMARY

I. Submitter

Submitter:	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:	September 22, 2022

II. Device

Name of Device:	8MP Color LCD Monitor CL-R813
Common or Usual Name:	Display, diagnostic radiology
Classification Name:	Medical Image Management and Processing System (Part 892 Radiology Devices Sec. 892.2050)
Regulatory Class	II
Product Code	PGY

III. Predicate Device

Name of Device:	21.3 inch (54.0cm) Color LCD Monitor CL-R211 (K182539)
Common or Usual Name:	Display, diagnostic radiology
Classification Name:	Medical Image Management and Processing System (Part 892 Radiology Devices Sec. 892.2050)
Regulatory Class	II
Product Code	PGY

IV. Device Description

32-inch 8MP Color LCD Monitor CL-R813, 3840 x 2160 (landscape)

- 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 mura correction functions will help achieve uniformity on the whole screen.

V. Indications for use

CL-R813 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.

VI. Cybersecurity

FDA guidance located at https://www.fda.gov/media/86174/download, is followed for cybersecurity concerns.

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VII. Comparison of Technological Characteristics with the predicate device

The comparison table below list information obtained from the product catalogs and measurements and different technological characteristics are discussed in it.

	Predicate device LCD Monitor CL-R211	Proposed device LCD Monitor CL-R813	Explanation of Differences
510(k) Number	K182539	–	–
Indication for use	CL-R211 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-R813 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: 32″ Aspect ratio: 16:9	The display area of the proposed device is larger than that of the predicate device.
Backlight type	LED	LED	–
Frame rate and refresh rate	60Hz	60Hz	–
Resolution / Pixel array	2MP (1200 x 1600)	8MP (3840 × 2160)	The resolution of the proposed device is higher than that of the predicate device.
Pixel Pitch	Horizontal: 0.270mm Vertical: 0.270mm	Horizontal: 0.1845mm Vertical: 0.1845mm	Pixel pitch of the proposed device are smaller than those of the predicate device.
Subpixel pattern	Stripe RGB	Stripe RGB	–
Pixel aperture ratio	57 %	57 %	–
Subpixel driving (spatial and temporal dithering)	N/A	N/A	–
Display Interface	Input: DVI-D x1 DisplayPort x1 Output: DisplayPort x1	Input: DVI-D x1 DisplayPort x2 Output: DisplayPort x1	–
Video bandwidth	Dot clock: 162 MHz	Dot clock: 533.25 MHz	So the resolution of the proposed device is higher than that of the predicate device, the dot clock of the proposed device is higher than that of the predicate device
User control	DICOM CONFORMANCE TEST Configuration switch Input signal switch Dynamic gamma AUTO TEXT Human presence sensor EDID switch Test pattern USB Power	Config Select Backlight Contrast Source Select Human Sensor	Although the user controls are different, the performance of the proposed device is the same as the predicate 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	–

The above differences in technical characteristics do not affect the safety and the effectiveness of the CL-R813.

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VIII. Performance Test

The following performance tests were performed on the CL-R813 in accordance with the instructions in "Guidance for Industry and FDA Staff: Display Devices for Diagnostic Radiology" issued on October 2, 2017.

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 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+AMD2:2021, 7.4.9 Greyscale chromaticity evaluation

As a result of the performance test, it was confirmed that the CL-R813 has the equivalent display characteristics as the predicate device, CL-R211. The display characteristics of the CL-R813 meet the predefined criteria.

The CL-R813 has not been tested on animal or clinical testing.

IX. Conclusions

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