



JVC Kenwood Corporation  
c/o Masafumi Yugami  
Manager  
3-12, Moriya-cho, Kanagawa-ku  
Yokohama, Kanagawa 221-0022  
JAPAN

October 3, 2018

Re: K182539

Trade/Device Name: 2MP Color LCD Monitor CL-R211  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture Archiving And Communications System  
Regulatory Class: Class II  
Product Code: PGY  
Dated: September 12, 2018  
Received: September 14, 2018

Dear Masafumi Yugami:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for  
Robert A. Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K182539

Device Name

2MP Color LCD Monitor CL-R211

Indications for Use (Describe)

CL-R211 (CL-R211xxxxx) 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.

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## 510(k) SUMMARY

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Submitted Information: JVC KENWOOD Corporation  
3-12, Moriya-cho, Kanagawa-ku,  
Yokohama-shi, Kanagawa, 221-0022 Japan

Contact Person: Masafumi Yugami, Manager  
Email: [yugami.masafumi@jvckenwood.com](mailto:yugami.masafumi@jvckenwood.com)  
Tel: +81-258-24-6611  
Fax: +81-258-24-6617

Date Prepared: September 12, 2018

Device Name: 2MP Color LCD Monitor CL-R211

Common Name: CL-R211 (CL-R211xxxxx)

Classification Name: Class II  
(Part 892 Radiology Devices  
Sec. 892.2050 Picture Archiving and Communication System)

Predicate Device: 21.3 inch (54cm) Color LCD Monitor CCL214  
(CL21214/ K161895)

Device Description: <Resolution>  
CL-R211 : 1600 x 1200 (landscape), 1200 x 1600 (portrait)  
  
DVI (digital interface) and DisplayPort (digital interface)

Intended 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.

Substantial Equivalence: CL-R211 shares the same technical characteristics, application, and  
intended use as our predicate device CCL214 (CL21214 / K161895)

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**JVC KENWOOD Corporation**

Healthcare Business Operation  
3-12, Moriya-cho, Kanagawa-ku,  
Yokohama-shi, Kanagawa, 221-0022 Japan

## Technical Specification

### 1. Luminance Response

[SPEC] Less than  $\pm 10\%$  based on AAPM-TG18 4.3.

### 2. Angular Dependencies

[SPEC] More than angle of  $20^\circ$   $LR'_{\delta, \theta} \geq 175$ ,  $k_{\delta, \theta} \leq 30\%$  based on AAPM-TG18 4.4.

### 3. Luminance Uniformity

[SPEC] Less than 30% based on AAPM-TG18 4.4.4

### 4. Pixel Defects / Fault

[SPEC] Class II or more. ISO13406-2

### 5. Artifacts

- phase/clock issues flicker
- miscellaneous including ringing, ghosting, image sticking

[SPEC] By visible check, no flicker, ringing, ghosting and image sticking.

### 6. Chromaticity Measurement of 5%, 50%, 95% Level

### 7. Chromaticity

[SPEC]  $\Delta(u', v') \leq 0.01$  measured at 80%  $L_{max}$  based on AAPM-TG18 4.8.4

### 8. Power On Luminance Drift

[SPEC]  $\Delta L_{max} \leq \pm 10\%$  within 60 seconds.

$\Delta L_{max}$  : the deviation between the target maximum luminance and the measured luminance.

### 9. Reflection

Based on AAPM-TG18 4.2.

### Substantial Equivalence Comparison

|                                        | <b>CCL214 (CL21214)</b>                                                                               | <b>CL-R211(CL-R211xxxxx)</b>                                                                          |
|----------------------------------------|-------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| <b>510(k) Number</b>                   | K161895                                                                                               | Not Known                                                                                             |
| <b>Resolution or Matrix Size</b>       | 2MP(1200 x 1600)                                                                                      | 2MP(1200 x 1600)                                                                                      |
| <b>Screen Technology</b>               | TFT Color LCD Panel (IPS)                                                                             | TFT Color LCD Panel (IPS)                                                                             |
| <b>Backlighting</b>                    | LED                                                                                                   | LED                                                                                                   |
| <b>Maximum Luminance</b>               | 500 cd/m2 typ.                                                                                        | 500 cd/m2 typ.                                                                                        |
| <b>DICOM<br/>Calibrated Luminance</b>  | 250 cd/m <sup>2</sup>                                                                                 | 250 cd/m <sup>2</sup>                                                                                 |
| <b>Viewing Angle</b>                   | CR>10:1<br>Horizontal: Typ.178 Vertical: Typ.178                                                      | CR>10:1<br>Horizontal: Typ.178 Vertical: Typ.178                                                      |
| <b>Display Area</b>                    | Horizontal: 432.0mm, Vertical: 324.0mm                                                                | Horizontal: 432.0mm, Vertical: 324.0mm                                                                |
| <b>Response Time (typical)</b>         | 10% – 90%<br>Ton 8ms Typ. Toff 8ms Typ.                                                               | 10% – 90%<br>Ton 8ms Typ. Toff 8ms Typ.                                                               |
| <b>Aspect Ratio</b>                    | 3:4                                                                                                   | 3:4                                                                                                   |
| <b>Pixel Pitch</b>                     | Horizontal: 0.270mm, Vertical: 0.270mm                                                                | Horizontal: 0.270mm, Vertical: 0.270mm                                                                |
| <b>Contrast Ratio</b>                  | 1200:1                                                                                                | 1800:1                                                                                                |
| <b>Grayscale Tones</b>                 | 10-bit (DisplayPort): 1,024from a palette of 65,473 tones<br>8-bit: 256 from a palette of65,473 tones | 10-bit (DisplayPort): 1,024from a palette of 65,473 tones<br>8-bit: 256 from a palette of65,473 tones |
| <b>Non-Uniformity<br/>Compensation</b> | Uniformity correction System                                                                          | Uniformity correction System                                                                          |
| <b>Input Video Signal</b>              | DVI-D 24-pin connector, DisplayPort connector                                                         | DVI-D 24-pin connector, DisplayPort connector                                                         |
| <b>USB Ports / Standard</b>            | USB: upstream port (x 1), downstream port (x 2)<br>Ver.2.0                                            | USB: upstream port (x 1), downstream port (x 2)<br>Ver.2.0                                            |

|                                         | <b>CCL214 (CL21214)</b>                                                                                                                                                                                                  | <b>CL-R211(CL-R211xxxxx)</b>                                                                                                                                                                                             |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Scanning Frequency</b>               | DVI<br>Horizontal:74.1KHz, Vertical: 60Hz (Landscape)<br>Horizontal:98.1KHz, Vertical: 60Hz (Portrait)<br>DisplayPort<br>Horizontal:75.0KHz, Vertical: 60Hz (Landscape)<br>Horizontal:99.0KHz, Vertical: 60Hz (Portrait) | DVI<br>Horizontal:74.1KHz, Vertical: 60Hz (Landscape)<br>Horizontal:98.1KHz, Vertical: 60Hz (Portrait)<br>DisplayPort<br>Horizontal:75.0KHz, Vertical: 60Hz (Landscape)<br>Horizontal:99.0KHz, Vertical: 60Hz (Portrait) |
| <b>Maximum Image Clock</b>              | 162MHz                                                                                                                                                                                                                   | 162MHz                                                                                                                                                                                                                   |
| <b>Rated</b>                            | AC100-240V, 50/60Hz<br>1.4 – 0.7A                                                                                                                                                                                        | AC100-240V, 50/60Hz<br><b>2.2 – 1.1A</b>                                                                                                                                                                                 |
| <b>Luminance Calibration (Optional)</b> | Software<br>Photo Sensor (optional): X-Rite i1Display                                                                                                                                                                    | Software<br>Photo Sensor (optional): X-Rite i1Display                                                                                                                                                                    |
| <b>Sensor</b>                           | Built-in Front Sensor                                                                                                                                                                                                    | Built-in Front Sensor                                                                                                                                                                                                    |
|                                         | Built-in Ambient Light Sensor                                                                                                                                                                                            | Built-in Ambient Light Sensor                                                                                                                                                                                            |
|                                         | None                                                                                                                                                                                                                     | Built-in Human presence sensor                                                                                                                                                                                           |
| <b>Safety Standards</b>                 | ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1,<br>FCC (Class B), ICES-003 (Class B),<br>MDD/CE, VCCI-B (Class B)                                                                                                        | ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1,<br>FCC (Class B), ICES-003 (Class B),<br>MDD/CE, VCCI-B (Class B)                                                                                                        |
| <b>Weight &amp; Dimension</b>           | Net: 11.1kg<br>367.0(w) x 521.9 – 583.4(H) x 220(D) mm<br>Packed: Approx.14.0kg<br>470(w) x 670(H) x 340.0(D) mm                                                                                                         | <b>Net: 8.9kg</b><br><b>361.5(w) x 517 – 612(H) x 196.5(D) mm</b><br><b>Packed: Approx.11.9kg</b><br><b>585(w) x 580(H) x 285(D) mm</b>                                                                                  |