DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 8, 2016

JVC KENWOOD Corporation
% Mr. Tsukasa Tashiro
Engineering Specialist
3-12, Moriya-cho, Kanagawa-ku
Yokohama, Kanagawa 221-0022
JAPAN

Re: K161895
Trade/Device Name: 2MP Color LCD Monitor CCL214 (CL21214)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: July 8, 2016
Received: July 11, 2016

Dear Mr. Tashiro:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161895

Device Name
2MP Color LCD Monitor CCL214 (CL21214)

Indications for Use *(Describe)*
2MP Color LCD Monitor CCL214 (CL21214)
is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners.
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

Submitted Information:	JVC KENWOOD Corporation 3-12, Moriya-cho, Kanagawa-ku, Yokohama-shi, Kanagawa, 221-0022 Japan
Contact Person:	Tsukasa Tashiro, Engineering Specialist Email: tashiro.tsukasa@jvckenwood.com Tel: +81-258-24-6611 Fax: +81-258-24-6617
Date Prepared:	July 08, 2016
Device Name:	2MP Color LCD Monitor CCL214 (CL21214)
Common Name:	CCL214 (CL21214)
Classification Name:	Class II (Part 892 Radiology Devices Sec. 892.2050 Picture Archiving and Communication System)
Predicate Device:	21.3 inch (54 cm) Color LCD Monitor CCL210 (CL21210) (K151134)
Device Description:	CCL214 (CL21214) is a 21.3-inch (54 cm) Color LCD monitor whose display resolution is 1600 x 1200 (landscape), 1200 x 1600 (portrait) supporting DVI-D (digital interface) and DisplayPort (digital interface).
Intended Use:	21.3 inch (54 cm) Color 2M pixel LCD Monitor, CCL214 (CL21214) is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners. It is not meant to be used in digital mammography.
Substantial Equivalence:	CCL214 (CL21214) shares the same technical characteristics, application, and intended use as our predicate device CCL210 (CL21210 / K151134).

Technical Specification

1. Luminance uniformity
   [SPEC] Less than 30% based on AAPM-TG18 4.4.

2. Pixel Defects / Fault
   [SPEC] Class II or more. ISO13406-2

3. Artifacts
   - phase/clock issues flicker
   - miscellaneous including ringing, ghosting, image sticking
     [SPEC] By visible check, no flicker, ringing, ghosting and image sticking.

4. Chromaticity Measurement of 5%, 50%, 95% Level

5. Chromaticity
   [SPEC] Delta (u', v') $\leqq$ 0.01 measured at 80% Lmax based on AAPM-TG18 4.8.4

6. Power On Luminance Drift
   [SPEC] $\triangle$Lmax$\leqq$±10% within 60 seconds.
   $\triangle$Lmax : the deviation between the target maximum luminance and the measured luminance.

Substantial Equivalence Comparison

	CCL210 (CL21210)	CCL214 (CL21214)
510(k) Number	K151134	Not Known
Display Area	Horizontal: 432.0mm, Vertical: 324.0mm	Horizontal: 432.0mm, Vertical: 324.0mm
Input Signal	DVI-I 29-pin connector, DisplayPort connector	DVI-D 24-pin connector, DisplayPort connector
Maximum Resolution	1200 x 1600 at portrait display 1600 x 1200 at landscape display	1200 x 1600 at portrait display 1600 x 1200 at landscape display
Pixel Pitch	0.270 mm x 0.270 mm	0.270 mm x 0.270 mm
Scanning Frequency	Horizontal: 30 – 75kHz Vertical: 55 – 60Hz	DVI Horizontal:74.1KHz, Vertical: 60Hz (Landscape) Horizontal:98.1KHz, Vertical: 60Hz (Portrait) DisplayPort Horizontal:75.0KHz, Vertical: 60Hz (Landscape) Horizontal:99.0KHz, Vertical: 60Hz (Portrait)
Maximum Image Clock	162MHz	162MHz
Maximum Luminance	250 cd/m^2 DICOM calibrated 440 cd/m^2 typ. As LCD component	250 cd/m^2 DICOM calibrated 500 cd/m^2 typ. As LCD component
Luminance Calibration (Optional)	Software Photo Sensor (optional): X-Rite Chroma 5	Software Photo Sensor (optional): X-Rite i1Display
Contrast Ratio	Typ 1500:1	Typ 1200:1
Serial Communication	USB	USB
Safety Standards	Medical Safety: ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1, FCC (Class B), MDD/CE, VCCI-B (Class B), ICES-003 (Class B)	Medical Safety: ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1, FCC (Class B), MDD/CE, VCCI-B (Class B), ICES-003 (Class B)
Weight & Dimension	Net: 10.7kg 473(w) x 476.4 – 537.9(H) x 220(D) mm Packed: 15.5kg 470(w) x 675(H) x 347(D) mm	Net: 11.1kg 367.0(w) x 521.9 – 583.4(H) x 220(D) mm Packed: Approx.14.0kg 470(w) x 670(H) x 340.0(D) mm
Power Supply	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz

Differences: The LCD panel, the power supply, and the main board for CCL214 (CL21214) are different from those for CCL210 (Predicated device).

Similarities: The tilt stand for CCL214 (CL21214) is the same as CCL210 (K151134).
But the sizes of front bezel and the rear cover are smaller than ones of CCL210 only slightly.

CCL214 (CL21214) can be considered to have equivalent performances to those of the predicate device CCL210 (K151134) due to the following reasons:

a. CCL214 (CL21214) and the predicate device CCL210 (K151134) have the same active area whose size is 432.0mm x 324.0mm.
   Also, the maximum display resolution for both models is 1600 x 1200.

b. As for the maximum luminance, CCL214 (CL21214) is superior to CCL210 (K151134).
   (CCL214 (CL21214): 500cd/m2 and CCL210 (K151134):440cd/m2)
   The maximum luminance by DICOM calibration at the factory default is 250cd/m2 for both CCL214 (CL21214) and the predicate device CCL210 (K151134).

c. The LED backlight is equipped with CCL214 (CL21214) and the predicate device CCL210 (K151134).

d. As the factory default status, the both devices display images in accordance with DICOM GSDF which is stored in the lookup table inside the device.

e. CCL214 (CL21214) supports DVI and DisplayPort as well as the predicate device CCL210（K151134）.

As for the maintenance, the same QC software is used for both devices.
CCL210 (K151134) has the backlight sensor to stabilize the luminance, but CCL214 (CL21214) has the front luminance sensor, which means the higher performance, to do so.

The overall design of the CCL214 (CL21214) has been validated in accordance with internationally recognized Safety and EMC standards by third-party certifiers.
Besides, JVC KENWOOD Corporation performed the system and performance tests to verify that the CCL214 (CL21214) performs in accordance with its specifications.
None of the tests revealed behaviors which is inconsistent with the expected performance.

Conclusion

The 2M pixel Color LCD Monitor, CCL214 (CL21214) is substantially equivalent to the predicate device with respect to technical characteristics, its application, its intended use, and the specifications of the primary components.
And other differences have been independently validated.
But any differences between these two devices do not affect safety or effectiveness.