DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 3, 2014

JVC KENWOOD CORPORATION
% Mr. Tsukasa Tashiro
Senior Manager
3-12 Moriya-cho, Kanagawa-ku
Yokohama-shi, Kanagawa, 221-0022
JAPAN

Re: K142536
Trade/Device Name: 21.5 inch (54.5 cm) Color LCD Monitor CCL220 (CL22220)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: September 5, 2014
Received: September 9, 2014

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

Janine M. Morris
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 on last page.

510(k) Number *(if known)*
Not known K142536

Device Name
CCL220 (CL22220)

Indications for Use *(Describe)*
21.5 inch (54.5 cm) Color 2M pixel LCD Monitor CCL220 (CL22220) is intended to be used in displaying and viewing medical images from PACS, endoscope and ultrasonograph 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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TOTOKU

510(k) SUMMARY

Submitted Information:	JVC KENWOOD CORPORATION 3-12, MORIYA-CHO, KANAGAWA-KU, YOKOHAMA-SHI, KANAGAWA, 221-0022 JAPAN
Contact Person:	Tsukasa Tashiro, Senior Manager Email: tashiro.tsukasa@jvckenwood.com Tel: +81.258.24.6611 Fax: +81.258.24.6617
Date Prepared:	September 5, 2014
Device Name:	21.5 inch (54.5 cm) Color LCD Monitor CCL220 (CL22220)
Common Name:	CCL220, CL22220
Classification Name:	Class II (Part 892 Radiology Devices Sec. 892.2050 Picture Archiving and Communication System)
Predicate Device:	20.1 inch (51 cm) Color LCD Monitor CCL208 (CDL2013A) (K092728).
Device Description:	CCL220 (CL22220) is a 21.5-inch (54.5 cm) Color LCD monitor whose display resolution is 1920 x 1080 (landscape), 1080 x 1920 (portrait) supporting multiple interfaces such as HDMI, BNC, S-video and HD-SDI in addition to DVI and D-Sub.
Intended Use:	21.5 inch (54.5 cm) Color 2M pixel LCD Monitor, CCL220 (CL22220) is intended to be used in displaying and viewing medical images from PACS, endoscope and ultrasonograph for diagnosis by trained Medical practitioners. It is not meant to be used in digital mammography.
Substantial Equivalence:	CCL220 (CL22220) shares the same technical characteristics and application with our predicate device CCL208 (K092728).

Technical Specification

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

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
   [SPEC] Refer to actual data.

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

6. Power On Luminance Drift
   [SPEC] Refer to actual data.

Substantial Equivalence Comparison

	CCL208 (CDL2013A)	CCL220 (CL22220)
510(k) Number	K092728	Not Known
Display Area	Horizontal: 408.0mm, Vertical: 306.0mm	Horizontal: 475.2mm, Vertical: 267.3mm
Input Signal	Mini D-sub 15-pin connector (same connector) DVI-I 29-pin connector	Mini D-sub 15-pin connector (same connector) DVI-I 24-pin connector, HDMI connector, BNC connector, S-Video connector, HD-SDI connector
Maximum Resolution	1200 x 1600 at portrait display 1600 x 1200 at landscape display	1080 x 1920 at portrait display 1920 x 1080 at landscape display
Scanning Frequency	Horizontal: 30 – 75kHz Vertical: 55 – 60Hz	Horizontal: 30 – 91kHz Vertical: 50 – 85Hz
Maximum Image Clock	162MHz	162MHz
Maximum Luminance	300cd/m^2	250cd/m^2
Luminance Calibration (Optional)	Software Photo Sensor (optional): X-Rite Chroma 5	Software Photo Sensor (optional): X-Rite Chroma 5
Serial Communication	DDC-ci based serial communication	RS-232C based serial communication (D-sub 9-pin)
Safety Standards	Medical Safety: MET (for US)/MET-C (for Canada), IEC60601-1, IEC60601-1-2, IEC60950-1, FCC- B, VCCI-B, MDD/CE	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), CCC
Weight & Dimension	Net: 10.7kg 453(w) x 462 - 523(H) x 220(D) mm Packed: 15.5kg 470(w) x 685(H) x 345(D) mm	Net: 5.1kg 513.4(w) x 305.8(H) x 74.3(D) mm Packed: 6.7kg 158(w) x 481(H) x 622(D) mm
Power Supply	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz

CCL220 (CL22220) can be considered to have equivalent display performances to those of the predicate device CCL208 (K092728) due to the following reasons:

a. CCL220 (CL22220) comes in a wider screen of 475.2mm x 267.3mm sized active display area with 1920*1080 sized maximum display compared to the predicate device CCL208 (K092728) with 408.0mm x 306.0mm active area and 1600*1200 sized maximum display.

b. The DICOM calibrated luminance value of the predicate device CCL208 (K092728) is 120cd/m2, whereas that of CCL220 (CL22220) is set to a higher value of 150cd/m2. In relation to the maximum luminance of the display, the proposed device CCL220 (CL22220) has the lower value of 250cd/m2 compared to the predicate device CCL208 (K092728) with 300cd/m2. However, CCL220 (CL22220) becomes capable of maintaining the brightness at the higher DICOM-calibrated luminance value for the same backlight life time as or even longer than the predicate device. This is achieved by adopting LED backlighting system, which lasts longer than the conventional CCFL's.

c. The LED backlight was newly employed instead of CCFL backlight because it is mercury-free, consumes less power and deteriorates more slowly. We have not recognized any adverse effects of the LED backlight on the quality of displayed images. Refer to "Technical Data" where several image quality characteristics of the proposed device are compared with those of the predicate device.

d. The both devices display images in accordance with DICOM GSDF by default utilizing the factory calibrated display mode stored in lookup tables inside of them.

e. The predicate device CCL208 (K092728) supports DVI (digital interface) and D-Sub (analog interface), while CCL220 (CL22220) is compatible with multiple interfaces such as HDMI, BNC, S-video and HD-SDI in addition to DVI and D-Sub.

As for the maintenance, QA software is used for both devices. Adopting the LED current stabilization circuit for luminance stabilization, CCL220 (CL22220) achieves equivalent or superior capability in stabilizing luminance to that of the predicate device CCL208 (K092728).

The overall design of the CCL220 (CL22220) was validated in accordance with internationally recognized Safety and EMC standards by third-party certifiers. Besides, JVC KENWOOD Corporation performed a range of system and performance tests to ensure that the CCL220 (CL22220) performs in accordance with its specifications. None of the tests revealed behaviors inconsistent with the expected performance.

Conclusion

The 2M pixel Color LCD Monitor, CCL220 (CL22220) is substantially equivalent to the predicate device with respect to technical characteristics and application. In terms of the intended use, the proposed device can be used for displaying medical images through endoscope and ultrasonograph besides PACS. The specifications of the primary component employed by the proposed device are the same as those of the predicate device and do not affect safety or effectiveness.