



Food and Drug Administration
10903 New Hampshire Avenue
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JVC KENWOOD Corporation
% Mr. Tsukasa Tashiro
Engineering Specialist
3-12, Moriya-cho, Kanagawa-ku
Yokohama-shi, Kanagawa 221-0022
JAPAN

May 8, 2015

Re: K151007
Trade/Device Name: 21.3 inch (54 cm) Color Digital Mammography LCD Monitor
CCL550i2 (CL21550)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: April 14, 2015
Received: April 15, 2015

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,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

Robert Ochs, Ph.D.
Acting 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)

K151007

Device Name

CCL550i2 (CL21550)

Indications for Use (Describe)

21.3 inch (54 cm) inch Color Digital Mammography 5M pixel LCD Monitor CCL550i2 (CL21550) is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners. It is to be used in digital mammography PACS 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.

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510(k) SUMMARY

Submitted Information: JVC KENWOOD CORPORATION
3-12, MORIYA-CHO, KANAGAWA-KU,
YOKOHAMA-SHI, KANAGAWA, 221-0022 JAPAN

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Date Prepared: April 14, 2015

Device Name: 21.3 inch (54 cm) inch Color Digital Mammography LCD Monitor
CCL550i2 (CL21550)

Common Name: CCL550i2, CL21550

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

Predicate Device: 21.3 inch (54 cm) inch Monochrome Digital Mammography LCD
Monitor MS55i2 (ML21055) (K131137)

Device Description: CCL550i2 (CL21550) is a 21.3 inch (54 cm) color LCD
monitor whose display resolution is 2048 x 2560 (landscape), 2560 x
2048 (portrait) supporting DVI (digital visual interface) and
DisplayPort.

Intended Use: 21.3 inch (54 cm) inch Color Digital Mammography 5M pixel LCD
Monitor CCL550i2 (CL21550) is intended to be used in displaying
and viewing medical images for diagnosis by trained medical
practitioners. It is to be used in digital mammography PACS and
modalities including FFDM.

Substantial Equivalence: CCL550i2 (CL21550) shares the same characteristics with our
predicate device MS55i2 (ML21055) (K131137) except for the LCD
panel and standard software.

JVC KENWOOD Corporation
Professional & Healthcare Division
3-12, Moriya-cho, Kanagawa-ku,
Yokohama-shi, Kanagawa, 221-0022 Japan

Display System Description

1. Active-Matrix Liquid-Crystal Displays (AMLCD) panel manufacturer, technology, Screen size and pixel pitch:
Screen size: 422.4(H)mm x 337.92(V) mm at landscape display, 337.92(H)mm x 422.4(V)mm at portrait display, Pixel pitch: 0.165mm(H) x 0.165mm(V) at landscape display, 0.165mm(H) x 0.165(V) at portrait display
 - Communicating ports:
Serial communication: USB (upstream x1, downstream x2)
2. Graphics card and software
 - Digital-to-Analog converters: speed and precision:
Only Digital operation, Digital to Analog converters are not provided.
 - Software included: calibration
JVCKENWOOD's calibration software called "FCAL" optimizes the display's performance using DICOM GSDF gamma and luminance. Calibration is recommended quarterly.
 - On-screen GUI: On-screen GUI is not provided.
 - Panel user controls: power switch

Technical Specification

1. Measuring Equipment
Refer to List.
2. Declared and actual (measured with test pattern in the screen) array size:
Declared array size (spec): 422.4(H)mm x 337.92(V) mm
Actual array size (measured): 422.7(H)mm x 338.0(V)mm
3. Luminance response
 - max and min achievable luminance:
[SPEC] Luminance Max (L_{max})=1000cd/m²,
Luminance Min (typ) = 0.77cd/m² at L_{max} =1000cd/m²
 - max and min recommended (operational) luminance:
[SPEC] Luminance Max recommend: $L_{max}(r)$ =500cd/m², $L_{min}(r)$ =0.8cd/m²
 - intrinsic bit-depth of the panel:
[SPEC] 10 bit per each pixel
 - true output bit-depth by performing visual test with gradient test pattern:
[SPEC] 10.0bit grayscale (1024 steps) achieved by 16bit LUT (Look-up Table) in the Display hardware.
 - intrinsic luminance response at 256 digital values:
[SPEC] dJND per dP<3.000, dJNDs/dP max error<2.000,
JNDs/P RMS error<1.000
Above spec is based on AAPM-TG18 Advanced Luminance Response, 4.3.5
Refer to actual luminance response data.
4. Angular Dependency
 - angular dependency of luminance:
[SPEC] $LR' \geq 175$, $K\delta > 30\%$
5. Luminance uniformity
[SPEC] Less than 30% based on AAPM-TG18 4.4. Refer to actual Luminance uniformity data.
6. Geometrical distortion
[SPEC] Less than 2.0% based on AAPM-TG18. Refer to actual Geometrical Distortion data.

7. Display reflectance

- Bi-directional reflection distribution function
[SPEC] Refer to Max allowable ambient luminance in Tables 4 and 5 on AAPM-TG18 4.2.4.
Refer to actual Reflectance Data.

8. Noise

- Pixel fill factor
[SPEC] 30% Min. Refer to Data of Pixel fill factor.
- Noise power spectrum (weiner spectrum)
[SPEC] Refer to actual data.

9. Veiling glare

[SPEC] Glare Ratio (GR) ≥ 400 $GR = (L_b - L_n) / (L - L_n)$ based on AAPM-TG18 4.7.4
Refer to actual veiling glare ratio data.

10. Chromaticity

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

11. Artifacts

- pixel dropouts including spatial distribution
[SPEC] Class (pixel) II. Refer to table 3 on 3.4.13 ISO13406-2.
- phase/clock issues flicker
- miscellaneous including ringing, ghosting, image sticking
[SPEC] By visible check, no ringing, ghosting image sticking

12. Spatial resolution, spatial MTF

[DATA] Refer to actual MTF data.

13. Temporal response

- rise and fall time constants for 5-95% and 40-60% transitions
[SPEC] Rise Time T_r , Fall Time T_f , $T_r, T_f < 55\text{ms}$. Refer to actual data.

14. Stability (possibly determined via temperature or time stress tests)

- of luminance response, of temporal response, of described artifacts
[SPEC] $K\delta$ within +/- 10% deviation to DICOM GSDF, based on AAPM-TG18 Luminance Response 4.3.4 via temperature stress 0 degC, 20 degC, 25 degC, 30 degC, 40 degC
Refer to actual measured data.

[fexos = for example, following ... or similar]

Substantial Equivalence Comparison

	5M Monochrome Digital Mammography LCD Monitor MS55i2 (ML21055, MD211G5)	5M Color Digital Mammography LCD Monitor CCL550i2 (CL21550)
510(k) Number	K131137	-
Display Area	Horizontal: 337.92mm, Vertical: 422.4mm	Horizontal: 337.92mm, Vertical: 422.4mm
Input Signal	DVI, DisplayPort	DVI, DisplayPort
Maximum Display	2048 x 2560 dots	2048 x 2560 dots
Scanning Frequency	Horizontal:129.1KHz Vertical:50Hz Portrait Horizontal:103.5KHz Vertical:50Hz Landscape	Horizontal:129.1KHz Vertical:50Hz Portrait Horizontal:103.5KHz Vertical:50Hz Landscape
Maximum Image Clock	285 MHz	285 MHz
Maximum Luminance (Calibrated Luminance)	Min.850cd/m ² Typ.1200cd/m ² . (as LCD component) (500cd/m ² - calibrated luminance)	Min.700cd/m ² Typ. 1000cd/m ² (as LCD component) (500cd/m ² calibrated luminance)
Contrast Ratio	Min.900 : 1 Typ.1200 : 1	Min.1000 : 1 Typ. 1300 : 1
Viewing Angle	CR>50 Typ.176 horizontal/vertical	CR>50 Typ.176 horizontal/vertical
Luminance Calibration (Optional)	Software (Standard): Medivisor Calibration Sensor (Optional): Chroma5 (X-Rite)	Software (Standard): FCAL Calibration Sensor (Optional): Chroma5 (X-Rite)
Serial Communication	USB: Downstream port x 2, Upstream port x 1	USB: Downstream port x 2, Upstream port x 1
Grayscale	10.3 bit (1276 gradation)	10.0 bit (1024 gradation)
Safety Standard	UL60601-1, CSA C22.2 No. 601-1, FCC-B, VCCI-B, MDD/CE,	ANSI/AAMI ES60601-1, CAN/CSA-C22.2 No. 60601-1, FCC-B, VCCI-B, MDD/CE,
Weight & Dimension	Net: approx. 12.8kg 474.5(W) x 480(H) x 220(D) mm (Landscape) 390(w) x 522(H) x 220(D) mm (Portrait) Packed: approx. 16.0 Kg 470(W) x 685 (H) x 345(D)	Net: approx.12.0Kg 474.5(W) x 480(H) x 220(D) mm (Landscape) 390(w) x 522(H) x 220(D) mm (Portrait) Packed: approx.15.0Kg 470(W) x 685 (H) x 345(D)
Power Supply	AC100-240V, 1.5-0.6A, 50/60Hz	AC100-240V, 1.5-0.6A, 50/60Hz

Similarities:

CCL550i2 (CL21550) employs the same driver board, tilt stand, power supply, etc. except of those of LCD Panel and standard software.

Differences:

CCL550i2 (CL21550) employs different LCD panel and standard software.

CCL550i2 (CL21550) can be considered to have equivalent display performances to those of the predicate device MS55i2 (ML21055) due to the following reasons:

- a. The maximum display sizes (2048*2560) and the active area sizes (337.92mm (H) x 422.4mm (V)) used for the both devices are the same.
- b. The DICOM calibrated luminance value of the both devices are the same (500 cd/m²) though the typical maximum luminance value (typ. 1000cd/m²) is lower than that of the predicate device (typ. 1200cd/m²). And Panels of the both devices are used LED backlight. The high luminance to be maintained constantly was realized by the employment of LED backlight deteriorating more slowly than conventional CCFL backlights. 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.
- c. 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.
- d. Both devices support Digital Visual Interface (DVI) and DisplayPort.
- e. As for the maintenance, the same QC software is used for both devices. Both devices have Front Sensor to stabilize the luminance.
- f. As for built-in sensors, both devices have 2 (two) kinds of common sensors, Front Sensor and Ambient Light Sensor. Front Sensor is related to the maintenance or calibration and Ambient Light Sensor is used to measure the ambient light by lx. Front sensor enables automatic grayscale calibration by measuring the luminance at the screen surface. Without Front sensor, the grayscale calibration process requires human intervention and the use of an external sensor. The accuracy data of the calibration with external sensors and that with Front Sensor is included in section 8 "Validation & Verification: Integration Test Report" and section 9 "Validation & Verification: System Test Report" in "Application".
- g. The overall design of the CCL550i2 (CL21550) 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 CCL550i2 (CL21550) performs in accordance with its specifications. None of the tests revealed behaviors inconsistent with the expected performance.

Conclusion

The 5M pixel Color LCD Monitor, CCL550i2 (CL21550) is substantially equivalent to the predicate device with respect to technical characteristics, application and intended use. The specifications of the primary components employed by the proposed device are the same to those of the predicate device except for the LCD panel, and the differences have been independently validated. Any differences between the devices do not affect safety or effectiveness.