



JVC KENWOOD Corporation
% Masafumi Yugami
Manager
3-12, Moriya-cho, Kanagawa-ku
Yokohama, Kanagawa 221-0022
JAPAN

December 14, 2017

Re: K173434

Trade/Device Name: 2MP Color LCD Monitor CL-S200, 3MP Color LCD Monitor CL-S300
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: November 17, 2017
Received: November 20, 2017

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. 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.

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.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Michael D. O'Hara 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

Indications for Use

510(k) Number (if known)

K173434

Device Name

2MP Color LCD Monitor CL-S200

3MP Color LCD Monitor CL-S300

Indications for Use (Describe)

CL-S200 (CL-S200xxxxx) and CL-S300 (CL-S300xxxxx) are 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

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

Contact Person: Masafumi Yugami, Manager
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Tel: +81-258-24-6611
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Date Prepared: November 1, 2017

Device Name: 2MP Color LCD Monitor CL-S200
3MP Color LCD Monitor CL-S300

Common Name: CL-S200 (CL-S200xxxxx)
CL-S300 (CL-S300xxxxx)

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-S200 : 1600 x 1200 (landscape), 1200 x 1600 (portrait)
CL-S300 : 2048 x 1536 (landscape), 1536 x 2048 (portrait)
DVI (digital interface) and DisplayPort (digital interface)

Intended Use: CL-S200 and CL-S300 are 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-S200 and CL-S300 share the same technical characteristics,
application, and intended use as our predicate device CCL214
(CL21214 / K161895)

JVC KENWOOD Corporation

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

Technical Specification

1. Angular Dependencies
[SPEC] More than angle of 20° $LR'_{\delta, \theta} \geq 175$, $k_{\delta, \theta} \leq 30\%$ based on AAPM-TG18 4.4.
2. Luminance Response
[SPEC] Less than 10% based on AAPM-TG18 4.3.
3. Luminance Uniformity
[SPEC] Less than 30% based on AAPM-TG18 4.4.4
4. Reflection
Based on AAPM-TG18 4.2.
5. Chromaticity
[SPEC] $\Delta(u', v') \leq 0.01$ measured at 80% L_{max} based on AAPM-TG18 4.8.4
6. Chromaticity Measurement of 5%, 50%, 95% Level
7. Artifacts
 - phase/clock issues flicker
 - miscellaneous including ringing, ghosting, image sticking[SPEC] By visible check, no flicker, ringing, ghosting and image sticking.
8. Pixel Defects / Fault
[SPEC] Class II or more. ISO13406-2
9. Power On Luminance Drift
[SPEC] $\Delta L_{max} \leq \pm 10\%$ within 60 seconds.
 ΔL_{max} : the deviation between the target maximum luminance and the measured luminance.

Substantial Equivalence Comparison

<CL-S200 (CL-S200xxxxx)>

	CCL214(CL21214)	CL-S200xxxxx
510(k) Number	K161895	—
Resolution or Matrix Size	2MP(1200 x 1600)	2MP(1200 x 1600)
Screen Technology	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)
Backlighting	LED	LED
Maximum Luminance	500 cd/m2 typ.	1000 cd/m2 typ.
DICOM Calibrated Luminance	250 cd/m ²	500 cd/m ²
Viewing Angle	CR>10:1 Horizontal: Typ.178 Vertical: Typ.178	CR>10:1 Horizontal: Typ.178 Vertical: Typ.178
Display Area	Horizontal: 432.0mm, Vertical: 324.0mm	Horizontal: 432.0mm, Vertical: 324.0mm
Response Time (typical)	10% – 90% Ton 8ms Typ. Toff 8ms Typ.	10% – 90% Ton 8ms Typ. Toff 8ms Typ.
Aspect Ratio	3:4	3:4
Pixel Pitch	Horizontal: 0.270mm Vertical: 0.270mm	Horizontal: 0.270mm Vertical: 0.270mm
Contrast Ratio	1200:1	1800:1
Grayscale Tones	10-bit (DisplayPort): 1,024 from a palette of 65,473 tones 8-bit: 256 from a palette of 65,473 tones	10-bit (DisplayPort): 1,024 from a palette of 65,473 tones 8-bit: 256 from a palette of 65,473 tones
Non-Uniformity Compensation	Uniformity correction System	Uniformity correction System
Input Video Signal	DVI-D x1 DisplayPort x1	DVI-D x1 DisplayPort x1
USB Ports / Standard	USB: upstream port (x 1), downstream port (x 2) Ver.2.0	USB: upstream port (x 1), downstream port (x 2) Ver.2.0
Scanning Frequency	DVI 74.1KHz, Vertical: 60Hz (Landscape) 98.1KHz, Vertical: 60Hz (Portrait) DisplayPort 75.0KHz, Vertical: 60Hz (Landscape) 99.0KHz, Vertical: 60Hz (Portrait)	DVI 74.1KHz, Vertical: 60Hz (Landscape) 98.1KHz, Vertical: 60Hz (Portrait) DisplayPort 75.0KHz, Vertical: 60Hz (Landscape) 99.0KHz, Vertical: 60Hz (Portrait)
Dot Clock	162 MHz	162 MHz

Rated	AC100-240V, 50/60Hz 1.4 – 0.7A	AC100-240V, 50/60Hz 2.2-1.1A
Luminance Calibration	Software: FCAL Calibration Sensor (Optional): i1 Display (X-Rite)	Software: FCAL Calibration Sensor (Optional): i1 Display (X-Rite)
Sensor	Built-in Front Sensor	Built-in Front Sensor
	Built-in Ambient Light Sensor	Built-in Ambient Light Sensor
	None	Built-in Human presence sensor
Safety Standards	ANSI/AAMI ES60601-1, CAN/CSA C22.2 No.60601-1, FCC (Class B), MDD/CE, VCCI-B (Class B)	ANSI/AAMI ES60601-1, CAN/CSA C22.2 No.60601-1, FCC (Class B), MDD/CE, VCCI-B (Class B)
Dimensions w/o Stand (W x H x D)	Net: 11.1kg 474(w) x 468.4 - 529.9(H) x 220(D) mm (Landscape) 367(w) x 524.9 - 586.4(H) x 220(D) mm (Portrait) Packed: 14.0kg 470(w) x 670(H) x 34(D) mm	Net: 9.2kg 493(w)x 451.3-546.3(H) x 196.5(D) mm (Landscape) 361.5(w) x 517-612(H)x 196.5(D) mm (Portrait) Packed: 12.0kg 585(w) x 580(H) x 285(D) mm

<CL-S300 (CL-S300xxxxx)>

	CCL214(CL21214)	CL-S300xxxxx
510(k) Number	K161895	—
Resolution or Matrix Size	2MP(1200 x 1600)	3MP(1536 x 2048)
Screen Technology	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)
Backlighting	LED	LED
Maximum Luminance	500 cd/m2 typ.	1000 cd/m2 typ.
DICOM Calibrated Luminance	250 cd/m ²	500 cd/m ²
Viewing Angle	CR>10:1 Horizontal: Typ.178 Vertical: Typ.178	CR>10:1 Horizontal: Typ.178 Vertical: Typ.178
Display Area	Horizontal: 432.0mm, Vertical: 324.0mm	Horizontal: 433.15mm, Vertical: 324.86mm
Response Time (typical)	10% – 90% Ton 8ms Typ. Toff 8ms Typ.	10% – 90% Ton 15ms Typ. Toff 15ms Typ.
Aspect Ratio	3:4	3:4
Pixel Pitch	Horizontal: 0.270mm Vertical: 0.270mm	Horizontal: 0.2115mm Vertical: 0.2115mm
Contrast Ratio	1200:1	1500:1
Grayscale Tones	10-bit (DisplayPort): 1,024 from a palette of 65,473 tones 8-bit: 256 from a palette of 65,473 tones	10-bit (DisplayPort): 1,024 from a palette of 65,473 tones 8-bit: 256 from a palette of 65,473 tones
Non-Uniformity Compensation	Uniformity correction System	Uniformity correction System
Input Video Signal	DVI-D x1 DisplayPort x1	DVI-D x1 DisplayPort x1
USB Ports / Standard	USB: upstream port (x 1), downstream port (x 2) Ver.2.0	USB: upstream port (x 1), downstream port (x 2) Ver.2.0
Scanning Frequency	DVI 74.1KHz, Vertical: 60Hz (Landscape) 98.1KHz, Vertical: 60Hz (Portrait) DisplayPort 75.0KHz, Vertical: 60Hz (Landscape) 99.0KHz, Vertical: 60Hz (Portrait)	DVI (Dual Link) 93.1KHz, Vertical: 60Hz (Landscape) 123.9KHz, Vertical: 60Hz (Portrait) DisplayPort 94.77KHz, Vertical: 59.98Hz (Landscape) 126.33KHz, Vertical: 59.96Hz

		(Portrait)
Dot Clock	162 MHz	216 MHz
Rated	AC100-240V, 50/60Hz 1.4 – 0.7A	AC100-240V, 50/60Hz 2.2-1.1A
Luminance Calibration	Software: FCAL Calibration Sensor (Optional): i1 Display (X-Rite)	Software: FCAL Calibration Sensor (Optional): i1 Display (X-Rite)
Sensor	Built-in Front Sensor	Built-in Front Sensor
	Built-in Ambient Light Sensor	Built-in Ambient Light Sensor
	None	Built-in Human presence sensor
Safety Standards	ANSI/AAMI ES60601-1, CAN/CSA C22.2 No.60601-1, FCC (Class B), MDD/CE, VCCI-B (Class B)	ANSI/AAMI ES60601-1, CAN/CSA C22.2 No.60601-1, FCC (Class B), MDD/CE, VCCI-B (Class B)
Dimensions w/o Stand (W x H x D)	Net: 11.1kg 474(w) x 468.4 - 529.9(H) x 220(D) mm (Landscape) 367(w) x 524.9 - 586.4(H) x 220(D) mm (Portrait) Packed: 14.0kg 470(w) x 670(H) x 34(D) mm	Net: 10.3kg 493(w) x 451.3-546.3(H) x 196.5(D) mm (Landscape) 361.5(w) x 517-612(H) x 196.5(D) mm (Portrait) Packed: 13.0kg 585(w) x 580(H) x 285(D) mm