



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

February 23, 2016

Re: K160326

Trade/Device Name: 5MP Monochrome LCD Monitor MS55i2 (ML21055, MD211G5)
5MP Color LCD Monitor CCL550i2 (CL21550)

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: PGY

Dated: January 29, 2016

Received: February 5, 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a grey shadow effect behind the text.

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)

K160326

Device Name

5MP Monochrome LCD Monitor MS55i2 (ML21055, MD211G5)

5MP Color LCD Monitor CCL550i2 (CL21550)

Indications for Use (Describe)

5MP Monochrome LCD Monitor MS55i2 (ML21055, MD211G5) and

5MP Color LCD Monitor CCL550i2 (CL21550)

are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners.

They are to be used in digital mammography PACS, modalities including FFDM, and breast tomosynthesis

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
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Date Prepared: January 29, 2016

Device Name: 1. 5MP Monochrome LCD Monitor MS55i2
(ML21055, MD211G5)
2. 5MP Color LCD Monitor CCL550i2
(CL21550)

Common Name: 1. MS55i2 (ML21055, MD211G5)
2. CCL550i2 (CL21550)

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

Predicate Device: 5MP Monochrome LCD Monitor, RadiForce GX540 (K151883)

Device Description: MS55i2 (ML21055, MD211G5) is a 21.3 inch (54 cm) monochrome LCD monitor and CCL550i2 (CL21550) is a 21.3 inch (54 cm) color LCD monitor. Their displays' resolution is 2048 x 2560 (landscape), 2560 x 2048 (portrait) supporting DVI (digital visual interface) and DisplayPort.

Intended Use: 5MP Monochrome LCD Monitor MS55i2 (ML21055, MD211G5) and 5MP Color LCD Monitor CCL550i2 (CL21550) are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners. They are to be used in digital mammography PACS, modalities including FFDM, and breast tomosynthesis

510(k) SUMMARY

Substantial Equivalence:

LCD Monitor MS55i2(ML21055, MD211G5)

	EIZO RadiForce GX540	LCD Monitor MS55i2 (ML21055, MD211G5)	Explanation of Differences
510(k) Number	K151883	K131137	-
Response Time (typical)	25ms (On/Off)	25ms (On/Off)	JVC KENWOOD uses typical data provided by the panel manufacturer. <u>For further explanation refer to temporal response of MS55i2.</u>
Resolution or Matrix Size	5MP(2048 x 2560)	5MP(2048 x 2560)	-
Screen Technology	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	-
Backlighting	LED	LED	-
Maximum Luminance	Min.850cd/m ² Typ.1200cd/m ² .	Min.850cd/m ² Typ.1200cd/m ² .	-
DICOM Calibrated Luminance	500cd/m ²	500cd/m ²	-
Viewing Angle	CR>50 Horizontal: Typ.176 Vertical: Typ.176	CR>50 Horizontal: Typ.176 Vertical: Typ.176	-
Display Area	Horizontal: 337.92mm Vertical: 422.4mm	Horizontal: 337.92mm Vertical: 422.4mm	-
Aspect Ratio	4:5	4:5	-
Pixel Pitch	Horizontal: 0.165mm Vertical: 0.165mm	Horizontal: 0.165mm Vertical: 0.165mm	-
Contrast Ratio	Min.900 : 1 Typ.1200 : 1	Min.900 : 1 Typ.1200 : 1	-
Grayscale Tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	10-bit (DisplayPort): 1,024 from a palette of 12,277 tones 8-bit: 256 from a palette of 12,277 tones	Maximum bit depth by Display port is 10 bit, it by DVI is 8 bit. Tone between the predicated device and our monitors are different. But our monitors pass the exams in AAPM-TG18 4.3 "Luminance Response". Our monitors are equivalent to the predicated device
Non-Uniformity Compensation	Digital Uniformity Equalizer (DUE)	Digital Uniformity correction System	Our Uniformity correction system is equivalent to the predicated device's one. This system is helpful to make visual performance much better in the point of luminance (monochrome and color version) and chromaticity.
Input Video Signal	DVI-D x1 DisplayPort x1	DVI-D x1 DisplayPort x1	-
Scanning Frequency	31 - 135 kHz / 24 - 61 Hz Frame synchronous mode: 24.5 - 25.5 Hz, 49 - 51 Hz	Portrait: Horizontal:129.1KHz Vertical:50Hz Landscape: Horizontal:103.5KHz	JVC KENWOOD specifies only maximum scanning frequency which is based on the LCD panel driving specification.

		Vertical:50Hz	
Dot Clock	290MHz	285 MHz	JVC KENWOOD specifies the dot clock which is based on the LCD panel driving specification.
Power Requirements	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	AC100-240V, 50/60Hz	JVC KENWOOD specification covers power requirement specification of the predicated device.
Power Consumption	108 W Less than 0.7 W	80W Less than 2W	-
Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a	-
QA Software	RadiCS	QA Medivisor / Medivisor NX F-CAL	
Sensor	Integrated Front Sensor (IFS)	Built- in Front Sensor	-
	Backlight Sensor (BS)	None	Brightness stability is controlled by the built-in Front sensor.
	Ambient Light Sensor (ALS)	Built-in ambient Light Sensor	-
	Presence Sensor (PS)	None	-
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
Dimensions w/o Stand (W x H x D)	388 x 496 x 99 mm	(AR, N) 474.5 x 390 x 98.1 mm (F) 474.5 x 390 x 103.7 mm	

MS55i2 adopts exactly the same panel as the predicated device, therefore its specification is completely same as the predicated device

LCD Monitor CCL550i2 (CL21550)

	EIZO RadiForce GX540	LCD Monitor CCL550i2 (CL21550)	Explanation of Differences
510(k) Number	K151883	K151007	-
Response Time (typical)	25ms (On/Off)	25ms (On/Off)	JVC KENWOOD uses typical data provided by the panel manufacturer. <u>For further explanation refer to temporal response of CCL550i2</u>
Resolution or Matrix Size	5MP(2048 x 2560)	5MP(2048 x 2560)	-
Screen Technology	TFT Monochrome LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
Backlighting	LED	LED	-
Maximum Luminance	Min.850cd/m ² Typ.1200cd/m ² .	Min.700cd/m ² Typ. 1000cd/m ²	Maximum luminance of color model is lower than monochrome panel.
DICOM Calibrated Luminance	500cd/m ²	500cd/m ²	However DICOM Calibrated luminance is same as the predicated device. Then actual performance for diagnosis is the same.
Viewing Angle	CR>50 Horizontal: Typ.176 Vertical: Typ.176	CR>50 Horizontal: Typ.176 Vertical: Typ.176	-
Display Area	Horizontal: 337.92mm Vertical: 422.4mm	Horizontal: 337.92mm Vertical: 422.4mm	-
Aspect Ratio	4:5	4:5	-
Pixel Pitch	Horizontal: 0.165mm Vertical: 0.165mm	Horizontal: 0.165mm Vertical: 0.165mm	-
Contrast Ratio	Min.900 : 1 Typ.1200 : 1	Min.1000 : 1 Typ. 1300 : 1	Contrast ratio of the color model is higher than the monochrome model.
Grayscale Tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	10-bit (DisplayPort): 1,024 from a palette of 65,473 tones 8-bit: 256 from a palette of 65,473 tones	Maximum bit depth by Display port is 10 bit, it by DVI is 8 bit. Tone between the predicated device and our monitors are different. But our monitors pass the exams in AAPM-TG18 4.3 "Luminance Response". Our monitors are equivalent to the predicated device
Non-Uniformity Compensation	Digital Uniformity Equalizer (DUE)	Digital Uniformity correction System	Our Uniformity correction system is equivalent to the predicated device's one. This system is helpful to make visual performance much better in the point of luminance (monochrome and color version) and chromaticity.
Input Video Signal	DVI-D x1 DisplayPort x1	DVI-D x1 DisplayPort x1	-
Scanning Frequency	31 - 135 kHz / 24 - 61 Hz Frame synchronous mode: 24.5 - 25.5 Hz, 49 - 51 Hz	Portrait: Horizontal:129.1KHz Vertical:50Hz Landscape: Horizontal:103.5KHz Vertical:50Hz	JVC KENWOOD specifies only maximum scanning frequency which is based on the LCD panel driving specification.
Dot Clock	290MHz	285 MHz	JVC KENWOOD specifies the dot clock which is based on the LCD panel driving specification.

Power Requirements	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	AC100-240V, 50/60Hz	JVC KENWOOD specification covers power requirement specification of the predicated device.
Power Consumption	108 W Less than 0.7 W	95W Less than 2W	-
Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a	-
QA Software	RadiCS	QA Medivisor / Medivisor NX F-CAL	
Sensor	Integrated Front Sensor (IFS)	Built- in Front Sensor	-
	Backlight Sensor (BS)	None	Brightness stability is controlled by the built-in Front sensor.
	Ambient Light Sensor (ALS)	Built-in ambient Light Sensor	-
	Presence Sensor (PS)	None	-
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
Dimensions w/o Stand (W x H x D)	388 x 496 x 99 mm	(AR, N) 474.5 x 390 x 98.1 mm (F) 474.5 x 390 x 103.7 mm	

Maximum luminance of the CCL550i2-panel is low, but calibrated luminance at the time of factory shipment state is 500cd/m2.

This value is same as the predicated one. Moreover, contrast ratio of CCL550i2-panel is better, and other specifications in comparison items are similar. Therefore, our monitor is equivalent to the predicated device.