



July 2, 2019

JVC Kenwood Corporation
% Hideki Tengeiji
Senior Manager
3-12, Moriya-cho, Kanagawa-ku
Yokohama-shi, Kanagawa 221-0022
JAPAN

Re: K191137

Trade/Device Name: 5MP Color LCD Monitor CL-S500, 5MP Monochrome LCD Monitor MS-S500
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: PGY
Dated: June 3, 2019
Received: Jun 5, 2019

Dear Hideki Tengeiji:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K191137

Device Name
5MP Color LCD Monitor CL-S500
5MP Monochrome LCD Monitor MS-S500

Indications for Use (Describe)

CL-S500 and MS-S500 are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. They're intended to be used in digital mammography PACS, digital breast tomosynthesis 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

K191137

Submitted Information: JVC KENWOOD Corporation
3-12, Moriya-cho, Kanagawa-ku,
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Contact Person: Hideki Tengeiji, Senior Manager
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Date Prepared: May 23, 2019

Device Name: 5MP Color LCD Monitor CL-S500
5MP Monochrome LCD Monitor MS-S500

Common Name: CL-S500 (CL-S500xxxxx)
MS-S500 (MS-S500xxxxx)

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 CCL550i2(CL21550)
(CCL550i2/ K160326)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY

Device Description: CL-S500 : 21.3 inch Color LCD Monitor
2048 x 2560 (landscape), 2560 x 2048 (portrait)
■ High-luminance color LCD panel, which has wide view angle, is used for this product. It is designed for medical image display.
■ Luminance stabilization function composed with luminance sensor and luminance control circuit always observes the luminance and makes it stable.
■ Images are faithfully displayed along grayscale characteristics (DICOM GSDF) based on the calibrated data stored to the lookup table of the monitor.
■ It minimizes luminance unevenness and color unevenness by Uniformity Correction Function to achieve the uniformity of

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luminance and color on the whole screen.

■ Quantitative evaluation and visual evaluation are done before the shipment. Quality control along the QC guideline is conducted

MS-S500 : 21.3 inch Monochrome LCD Monitor

2048 x 2560 (landscape), 2560 x 2048 (portrait)

■ High-luminance monochrome LCD panel, which has wide view angle, is used for this product. It is designed for medical image display.

■ Luminance stabilization function composed with luminance sensor and luminance control circuit always observes the luminance and makes it stable.

■ Images are faithfully displayed along grayscale characteristics (DICOM GSDF) based on the calibrated data stored to the lookup table of the monitor.

■ It minimizes luminance unevenness by Uniformity Correction Function to achieve the uniformity of luminance on the whole screen.

■ Quantitative evaluation and visual evaluation are done before the shipment. Quality control along the QC guideline is conducted.

Intended Use: CL-S500 and MS-S500 are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel.

They're intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

Substantial Equivalence: CL-S500 and MS-S500 share the same technical characteristics, application, and intended use as our predicate device CCL550i2/ K160326.

Conclusion: CL-S-500 and MS-S500 are substantially equivalent to the predicate device with respect to technical characteristics, application and intended use.

The specifications of the primary component employed by the proposed device are the same as those of the predicate device, and other differences have been independently validated. Any differences between the devices do not affect safety or effectiveness.

Substantial Equivalence Comparison

This comparison table shows the differences on the technical characteristics between the proposed devices and the predicate device.

<CL-S500>

	Predicate device LCD Monitor CCL550i2 (CL21550)	LCD Monitor CL-S500	Explanation of Differences
510(k) Number	K160326	K191137	-
Indication for use	CCL550i2 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, digital breast tomosynthesis and modalities including FFDM.	CL-S500 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It is intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.	
Response Time (typical)	25ms (On/Off)	25ms (On/Off)	-
Resolution or Matrix Size	5MP(2048 x 2560)	5MP(2048 x 2560)	-
Screen Technology	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
Backlighting	LED	LED	-
Maximum Luminance	Min.700cd/m ² Typ. 1000cd/m ²	Min. 920cd/m ² Typ. 1,150cd/m ²	The maximum luminance of the predicate device is Min.700cd/m ² and one of CL-S500 is Min.920cd/m ² . Therefore, CL-S500 is equivalent to or better than the predicate device.
DICOM Calibrated Luminance	500cd/m ²	500cd/m ²	
Viewing Angle	CR>50 Horizontal: Typ.176 Vertical: Typ.176	CR>50 Horizontal: Typ.178 Vertical: Typ.178	Compared with the predicate device, CL-S500 is equivalent to or better than the predicate device.

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.1000 : 1 Typ. 1300 : 1	Min.1600 : 1 Typ. 2000 : 1	The contrast ratio is the predicate device is Typ.1300:1, and the one of the proposed device CL-S500 is Typ.1600:1. Therefore, CL-S500 is equivalent to or better than the predicate device.
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): 1.073 billion 1024 from a palette of 16,369 tones 8-bit(DVI): 16.77 million 256 from a palette of 16,369 tones	-
Non-Uniformity Compensation	Digital Uniformity correction System	Digital Uniformity correction System	-
Input Video Signal	DVI-D x1 DisplayPort x1	DVI-D x1 DisplayPort x1	-
Scanning Frequency	Portrait: Horizontal:129.1KHz Vertical:50Hz Landscape: Horizontal:103.5KHz Vertical:50Hz	Portrait: Horizontal:129.1KHz Vertical:50Hz Landscape: Horizontal:103.5KHz Vertical:50Hz	-
Dot Clock	285 MHz	285 MHz	-
Power Requirements	AC100-240V, 50/60Hz	AC100-240V, 50/60Hz	-
Power Consumption	95W Less than 2W	95W Less than 1W	-
Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.2a	-
QA Software	QA Medivisor / Medivisor NX F-CAL	QA Medivisor / Medivisor NX F-CAL	-
Sensor	Built- in Front Sensor	Built- in Front Sensor	-

	Built-in ambient Light Sensor	Built-in ambient Light Sensor	-
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)	(AR, N) 474.5 x 390 x 98.1 mm (F) 474.5 x 390 x 103.7 mm	(G) 361.5 x 517/612 x 196.5 mm	

<MS-S500>

	Predicate device LCD Monitor CCL550i2 (CL21550)	LCD Monitor MS-S500	Explanation of Differences
510(k) Number	K160326	K191137	-
Indication for use	CCL550i2 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, digital breast tomosynthesis and modalities including FFDM.	MS-S500 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It is intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.	
Response Time (typical)	25ms (On/Off)	25ms (On/Off)	
Resolution or Matrix Size	5MP(2048 x 2560)	5MP(2048 x 2560)	-
Screen Technology	TFT Color LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	The difference between monochrome and color
Backlighting	LED	LED	-
Maximum Luminance	Min.700cd/m ² Typ. 1000cd/m ²	Min. 2,400cd/m ² Typ. 3,000cd/m ²	The maximum luminance of the predicate device is Min.700cd/m ² and one of MS-S500 is Min.2400cd/m ² .

DICOM Calibrated Luminance	500cd/m ²	1,000 cd/m ²	Therefore, MS-S500 is equivalent to or better than the predicate device. The calibrated luminance of the predicate device is Min.500cd/m ² and one of MS-S500 is Min.1000cd/m ² . Therefore, MS-S500 is equivalent to or better than the predicate device.
Viewing Angle	CR>50 Horizontal: Typ.176 Vertical: Typ.176	CR>50 Horizontal: Typ.178 Vertical: Typ.178	Compared with the predicate device, MS-S500 is equivalent to or better than the predicate device.
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.1000 : 1 Typ. 1300 : 1	Min.1600 : 1 Typ.2000 : 1	The contrast ratio is the predicate device is Typ.1300:1, and the one of the proposed device MS-S500 is Typ.2000:1. Therefore, MS-S500 is equivalent to or better than the predicate device.
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 16,369 tones 8-bit (DVI) : 256 from a palette of 16,369 tones	Maximum bit depth by DisplayPort is 10 bit, and one by DVI is 8 bit. Tone between the predicate device and our proposed devices are different. But they pass the exams in AAPM-TG18 4.3 "Luminance Response". Therefore, they are equivalent to the predicate device.
Non-Uniformity Compensation	Digital Uniformity correction System	Digital Uniformity correction System	-
Input Video Signal	DVI-D x1 DisplayPort x1	DVI-D x1 DisplayPort x1	-
Scanning Frequency	Portrait: Horizontal:129.1KHz Vertical:50Hz Landscape: Horizontal:103.5KHz Vertical:50Hz	Portrait: Horizontal:129.1KHz Vertical:50Hz Landscape: Horizontal:103.5KHz Vertical:50Hz	-
Dot Clock	285 MHz	285 MHz	-
Power Requirements	AC100-240V, 50/60Hz	AC100-240V, 50/60Hz	-

Power Consumption	95W Less than 2W	80W Less than 1W	-
Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.2a	-
QA Software	QA Medivisor / Medivisor NX F-CAL	QA Medivisor / Medivisor NX F-CAL	
Sensor	Built- in Front Sensor	Built- in Front Sensor	-
	Built-in ambient Light Sensor	Built-in ambient Light Sensor	-
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)	(AR, N) 474.5 x 390 x 98.1 mm (F) 474.5 x 390 x 103.7 mm	(G) 361.5 x 517/612 x 196.5 mm	

Recommended Physical Laboratory Tests

Measurements Guidance	MS-S500, CL-S500 Measurements
a. Spatial resolution	MTF measurement method that uses a bar-pattern image. (Rectangle chart method)
b. Pixel defects (maximum counts, allowed defect types, and locations)	ISO13406-2 and Flat Panel Display Measurement Standard [VESA 2001] were used.
c. Artifacts	Artifacts (phase or clock, ringing, ghosting, image sticking, etc.)
d. Temporal response	JVC KENWOOD uses typical data provided by the panel manufacturer. (5-95%, 10-90%, 40-60%)
e. Luminance (maximum, minimum, achievable, and recommended)	Lmin, and Lmax on the calibrated luminance was confirmed by the requirement of the "Luminance Response" test of AAPM-TG18.
f. Conformance to a grayscale-to-luminance function (e.g., DICOM GSDF)	Luminance Response at 256 digital values by AAPM-TG18
g. Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and four corners	Angular dependency of luminance by AAPM-TG18
h. Luminance uniformity or Mura test	Luminance Uniformity by AAPM-TG18 Chromaticity by AAPM-TG18
i. Stability of luminance and chromaticity response with temperature and time of operation or on-time	0°C, 25°C, and 40°C on Luminance response by AAPM-TG18 (Power On Drift.)
j. Spatial noise	Noise Power Spectrum
k. Reflection coefficient	Specular reflection and Diffuse reflection by AAPM-TG18
l. Veiling glare or small-spot contrast	Veiling Glare test by AAPM-TG18
Other	Pixel fill factor (Pixel structure and aperture ratio of pixel.