February 21, 2020

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

Re: K200161
Trade/Device Name: 3MP Monochrome Digital Mammography LCD Monitor MS-S300
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 16, 2020
Received: January 22, 2020

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200161

Device Name
3MP Monochrome Digital Mammography LCD Monitor MS-S300

Indications for Use *(Describe)*
MS-S300 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It's 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 K200161

Submitted Information:	JVCKENWOOD Corporation 3-12, Moriya-cho, Kanagawa-ku, Yokohama-shi, Kanagawa, 221-0022 Japan
Contact Person:	Hideki Tengeiji, Senior Manager Email: tengeiji.hideki@jvckenwood.com Tel: +81-45-450-2715 Fax: +81-45-450-1926
Date Prepared:	January 16, 2020
Device Name:	3MP Monochrome Digital Mammography LCD Monitor MS-S300
Common Name:	MS-S300 (MS-S300xxxxx)
Classification Name:	Class II (Part 892 Radiology Devices Sec. 892.2050 Picture Archiving and Communication System)
Predicate Device:	21.3 inch (54cm) Monochrome LCD Monitor MS35i2 (MS35i2/ K133686)
Device Description:	21.3 inch Monochrome Digital Mammography LCD Monitor 2048 x 1536 (landscape), 1536 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.

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Intended Use:	MS-S300 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It's intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.
Substantial Equivalence:	MS-S300 shares the same technical characteristics, application, and intended use as our predicate device MS35i2/ K133686.
Conclusion:	MS-S300 is substantially equivalent to the predicate device with respect to technical characteristics, application and intended use. The specification of the primary component employed by the proposed device is the same as one of the predicate device, and other differences have been independently validated. Any differences between the devices do not affect safety or effectiveness.

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Substantial Equivalence Comparison

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

<MS-S300>

	Predicate device LCD Monitor MS35i2 (ML21035)	**LCD Monitor MS-S300**	**Explanation of Differences**
510(k) Number	K133686	—	—
Indication for Use	MS35i2 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It is to be used in digital mammography PACS and modalities including FFDM.	MS-S300 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)	40ms (On/Off)	28ms (On/Off)	Response Time of MS-S300 is better than the predicate's one.
Resolution or Matrix Size	3MP(1536 x 2048)	3MP(1536 x 2048)	—
Screen Technology	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	—
Backlighting	LED	LED	—
Maximum Luminance	Typ. 1700cd/m^2	Typ. 2000cd/m^2	The maximum luminance of MS-S300 is much better than the predicate's one.
DICOM Calibrated Luminance	500cd/m^2	500cd/m^2	—
Viewing Angle	CR>10 Horizontal: Typ.176 Vertical: Typ.176	CR>10 Horizontal: Typ.178 Vertical: Typ.178	Viewing angle of MS-S300 is wider than the predicate's one.
Display Area	Horizontal: 324.86mm Vertical: 433.15mm	Horizontal: 324.86mm Vertical: 433.15mm	—
Aspect Ratio	3:4	3:4	—
Pixel Pitch	Horizontal: 0.2115mm Vertical: 0.2115mm	Horizontal: 0.2115mm Vertical: 0.2115mm	—

Contrast Ratio	Typ. 1400:1	Typ. 1500:1	Contrast ratio of MS-S300 is wider than the predicate's one
Grayscale Tones	10.3 bit: (1276 gradation)	10.3 bit: (1276 gradation)	—
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	DVI 46.6KHz, Vertical: 30Hz (Landscape) 61.9KHz, Vertical: 30Hz (Portrait) 93.1KHz, Vertical: 60Hz (Landscape) 123.9KHz, Vertical: 60Hz (Portrait) DisplayPort 47.4KHz, Vertical: 30Hz (Landscape) 63.2KHz, Vertical: 30Hz (Portrait) 94.8KHz, Vertical: 60Hz (Landscape) 126.3KHz, Vertical: 60Hz (Portrait)	DVI 46.6KHz, Vertical: 30Hz (Landscape) 61.9KHz, Vertical: 30Hz (Portrait) 93.1KHz, Vertical: 60Hz (Landscape) 123.9KHz, Vertical: 60Hz (Portrait) DisplayPort 47.4KHz, Vertical: 30Hz (Landscape) 63.2KHz, Vertical: 30Hz (Portrait) 94.8KHz, Vertical: 60Hz (Landscape) 126.3KHz, Vertical: 60Hz (Portrait)	—
Dot Clock	216 MHz	216 MHz	—
Power Requirements	AC100-240V, 50/60Hz	AC100-240V, 50/60Hz	—
Power Consumption	60W Less than 2W	55W Less than 2W	Power consumption on MS-S300 is less than the predicate's one.
Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.2a	—
QA Software	Medivisor NX F-CAL	QA Medivisor Agent F-CAL	"QA Medivosior Agent" is the later software of "Medivisor NX".
Sensor	Built- in Front Sensor	Built- in front sensor	—
	Built-in ambient Light Sensor	Built-in ambient light sensor	—
		Built-in human presence sensor	Used for the power save function.
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	—
Dimensions with Stand (W x H x D)	367.0 x 522/583 x 220.0 mm	361.5 x 517.0 / 612.0 x 196.5 mm	—

Recommended Physical Laboratory Tests

Measurements Guidance	MS-S300 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	JVCKENWOOD 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℃, 25℃, and 40℃ 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.