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

April 23, 2021

Re: K210345
Trade/Device Name: 2MP Monochrome LCD Monitor MS-S200
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: PGY
Dated: January 29, 2021
Received: February 5, 2021

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K210345

Device Name
2MP Monochrome LCD Monitor MS-S200

Indications for Use *(Describe)*
MS-S200 is 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) SUMMARY

K210345


Submitted Information: JVCKENWOOD Corporation
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Contact Person: Hideki Tengeiji, Senior Manager
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Date Prepared: April 13, 2021

Device Name: 2MP Monochrome LCD Monitor MS-S200

Common Name: MS-S200 (MS-S200xxxxx)

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 MS25i2 (ML21025)
(MS25i2/ K133511)

Device Description: 21.3 inch (54cm) Monochrome LCD Monitor
1600 x1200 (landscape)

■ 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-S200 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel.<br>It is not meant to be used in digital mammography. |
| Substantial Equivalence: | MS-S200 shares the same technical characteristics, application, and intended use as our predicate device MS25i2/K133511. |
| Validation for Performance Specification: | All items in monitor specification have met the acceptance criteria according to the standard, AAPM-TG18 and ISO 13406-2. |
| Changes in the new monitor, MS-S200: | 1) Response Time<br>19 ms (new monitor:MS-S200) vs. 40 ms (predicate device:MS25i2)<br>The specification of the proposed device (MS-S200) is superior to that of the predicate device (MS25i2).<br>2) Contrast Ratio<br>1800:1 (new monitor:MS-S200) vs. 1400:1 (predicate device:MS25i2)<br>The specification of the proposed monitor (MS-S200) is superior to that of the predicate device (MS25i2) |
| Conclusion: | Based on our specification confirmation and physical evaluation as above, the proposed device is substantial equivalent to the predicate device. |

**JVCKENWOOD Corporation**
Healthcare Business Division
3-12, Moriya-cho, Kanagawa-ku,
Yokohama-shi, Kanagawa, 221-0022 Japan

## Substantial Equivalence Comparison

| | Predicate Device<br>MS25i2 (ML21025) | Proposed Device<br>MS-S200 (MS-S200xxxxx) | Explanation of Differences |
|---|---|---|---|
| **510(k) Number** | K133511 | Not Known | — |
| **Indication for Use** | 21.3 inch (54 cm) Monochrome 2M pixel LCD Monitor MS25i2 (ML21025) is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel.<br>It is not meant to be used in digital mammography. | 21.3 inch (54 cm) Monochrome 2M pixel LCD Monitor MS-S200 (MS-S200xxxxx) is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel.<br>It is not meant to be used in digital mammography. | — |
| **Resolution or Matrix Size** | Portrait : 1200 x 1600 (4800 subpixel)<br>Landscape : 1600 (4800 subpixel) x 1200 | Portrait : 1200 x 1600 (4800 subpixel)<br>Landscape : 1600 (4800 subpixel) x 1200 | — |
| **Screen Technology** | TFT Monochrome LCD Panel (IPS) | TFT Monochrome LCD Panel (IPS) | — |
| **Backlighting** | LED | LED | — |
| **Maximum Luminance** | 1900 cd/m$^2$ typ. | 1900 cd/m$^2$ typ. | — |
| **DICOM Calibrated Luminance** | 0.8 - 410 cd/m$^2$ | 0.8 - 410 cd/m$^2$ | — |
| **Viewing Angle** | CR>10:1<br>Viewing angle :<br>Horizontal: Typ.176 Vertical: Typ.176 | CR>10:1<br>Viewing angle :<br>Horizontal: Typ.178 Vertical: Typ.178 | The specification of the proposed device is superior to that of the predicate device. |
| **Display Area** | Horizontal: 324.0 mm, Vertical: 432.0 mm | Horizontal: 324.0 mm, Vertical: 432.0 mm | — |

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|---|---|---|---|
| **Response Time (typical)** | T on + T off (10% – 90%)<br>40 ms typ. | T on + T off (10% – 90%)<br>19 ms typ. | The specification of the proposed device is superior to that of the predicate device. |
| **Aspect Ratio** | 3:4 | 3:4 | — |
| **Pixel Pitch** | Horizontal: 0.270 mm, Vertical: 0.270 mm | Horizontal: 0.270 mm, Vertical: 0.270 mm | — |
| **Contrast Ratio** | 1400:1 | 1800:1 | The specification of the proposed device is superior to that of the predicate device. |
| **Grayscale Tones** | 10.3 bit (1276 gradation) | 10.3 bit (1276 gradation) | — |
| **Non-Uniformity Compensation** | N/A | N/A | — |
| **Input Video Signal** | DVI-D, DisplayPort | DVI-D, DisplayPort | — |
| **USB Ports / Standard** | USB:<br>Upstream port (x1), Downstream port (x2)<br>Ver.2.0 | USB:<br>Upstream port (x1), Downstream port (x2)<br>Ver.2.0 | — |
| **Scanning Frequency** | DVI<br>74.1KHz, Vertical: 60Hz (Landscape)<br>98.1KHz, Vertical: 60Hz (Portrait)<br>DisplayPort<br>75.0KHz, Vertical: 60Hz (Landscape)<br>99.0KHz, Vertical: 60Hz (Portrait) | DVI<br>74.1KHz, Vertical: 60Hz (Landscape)<br>98.1KHz, Vertical: 60Hz (Portrait)<br>DisplayPort<br>75.0KHz, Vertical: 60Hz (Landscape)<br>99.0KHz, Vertical: 60Hz (Portrait) | — |
| **Maximum Image Clock** | 162MHz | 162MHz | — |
| **Rated** | AC100-240V, 50/60Hz 1.5 – 0.6A | AC100-240V, 50/60Hz 2.2 – 1.1A | The difference does not affect diagnosis. |

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|---|---|---|---|
| **Luminance Calibration (Optional)** | Software: Medivisor Nx<br>Calibration Sensor (Optional): Chroma5 (X-Rite) | Software: F-CAL, Medivisor Agent<br>Calibration Sensor (Optional): i1Display (X-Rite) | Application software and calibration sensor of the proposed device currently support those of the predicate device. |
| **Sensor** | Built-in Front Sensor | Built-in Front Sensor | Adding human presence sensor does not affect diagnosis, only for energy saving. |
| | 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), ICES-003 (Class B), MDD/CE, VCCI-B (Class B) | ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1, FCC (Class B), ICES-003 (Class B), MDR/CE, RCM, VCCI-B (Class B) | Safety standards of the predicate device currently support those of the proposed device.<br>(RCM is added) |
| **Weight & Dimension** | Net: Approximately 12.0kg<br><br>Landscape:<br>474.0 (w) x 468.4 - 529.9 (H) x 220.0 (D) mm<br><br>Portrait:<br>367.0 (w) x 521.9 - 583.4 (H) x 220.0 (D) mm<br><br>Packed: Approximately 15.0kg<br>470 (W) x 670 (H) x 340 (D) mm | Net: Approximately 9.3 kg (Filter Model)<br>Approximately 8.9 kg (Normal Model)<br><br>Landscape:<br>493.0 (w) x 451.3 – 546.3 (H) x 196.5 (D) mm<br><br>Portrait:<br>361.5 (w) x 517.0 – 612.0 (H) x 196.5 (D) mm<br><br>Packed: Approximately 12.3kg (Filter Model)<br>Approximately 11.9kg (Normal Model)<br>585 (W) x 580 (H) x 285 (D) mm | The difference does not affect diagnosis. |