K133686
Page 1 of 4

JAN - 6 2014

TOTOKU

510(k) SUMMARY

Submitted Information:	JVC KENWOOD CORPORATION 3-12, MORIYA-CHO, KANAGAWA-KU, YOKOHAMA-SHI, KANAGAWA, 221-0022 JAPAN
Contact Person:	Tsukasa Tashiro, General Manager Email: tashiro.tsukasa@jvckenwood.com Tel: +81.258.24.6611 Fax: +81.258.24.6617
Date Prepared:	November 29, 2013
Device Name:	21.3 inch (54 cm) inch Monochrome Digital Mammography LCD Monitor MS35i2 (ML21035)
Common Name:	MS35i2, ML21035
Classification Name:	Class II (Part 892 Radiology Devices Sec. 892.2050 Picture Archiving and Communication System)
Predicate Device:	20.8 inch Monochrome Digital Mammography LCD Monitor MS33i2 (ML21033) (K112145).
Device Description:	MS35i2 (ML21035) is a 21.3 inch (54 cm) monochrome LCD monitor whose display resolution is 1536 x 2048 (landscape), 2048 x 1536 (portrait) supporting DVI (digital visual interface) and DisplayPort.
Intended Use:	21.3 inch (54 cm) inch Monochrome Digital Mammography 3M pixel LCD Monitor with sub-pixel driving techniques enabling 9M subpixels to be driven independently, MS35i2 (ML21035) 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 and modalities including FFDM.
Substantial Equivalence:	MS35i2 (ML21035) shares the same characteristics with our predicate device MS33i2 (K112145) except for the front bezel, LCD panel and power supply.

JVC KENWOOD Corporation
Professional & Healthcare Division
3-12, Moriya-cho, Kanagawa-ku,
Yokohama-shi, Kanagawa, 221-0022 Japan

Substantial Equivalence Comparison

	20.8 inch Monochrome Digital Mammography LCD Monitor MS33i2 (ML21033)	**21.3 inch Monochrome Digital Mammography LCD Monitor MS35i2 (ML21035)**
510(k) Number	K112145	Not Known
Display Area	Horizontal: 318.0mm, Vertical: 423.9mm Vertical: 423.9mm, Horizontal: 318.0mm	Horizontal: 324.864mm, Vertical: 433.152mm Vertical: 433.152mm, Horizontal: 324.864mm
Input Signal	DVI-D, DisplayPort	DVI-D, DisplayPort
Maximum Display	1536 x 6144 (Sub-pixel) dots at portrait display 6144 (Sub-pixel) x 1536 dots at landscape display	1536 x 6144 (Sub-pixel) dots at portrait display 6144 (Sub-pixel) x 1536 dots at landscape display
Pixel Pitch	0.207mm x 0.207mm	0.2115mm x 0.2115mm
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)
Maximum Image Clock	216MHz	216MHz
Maximum Luminance	1000 cd/m^2	1700 cd/m^2
Luminance Calibration (Optional)	Software: Medivisor Nx Calibration Sensor (Optional): Chroma5 (X-Rite)	Software: Medivisor Nx Calibration Sensor (Optional): Chroma5 (X-Rite)
Contrast Ratio	900:1	1400:1
Serial Communication	USB: Downstream port x 2, Upstream port x 1	USB: Downstream port x 2, Upstream port x 1
Grayscale	10.3 bit (1276 gradation)	10.3 bit (1276 gradation)
Safety Standard	UL60601-1, CSA C22.2 No. 601-1, FCC-B, VCCI-B, MDD/CE,	ANSI/AAMI ES60601-1, CAN/CSA C22.2 No.60601-1, FCC (Class B), MDD/CE, VCCI-B (Class B)
Weight & Dimension	Net: Approximately 12kg 474(W) x 468/530(H) x 220(D) mm (Landscape) 367(w) x 522/583(H) x 220(D) mm (Portrait) Packed: Approximately 15Kg, 470(W) x 685 (H) x 345(D)	Net: Approximately 12kg 474(W) x 468/530(H) x 220(D) mm (Landscape) 367(w) x 522/583(H) x 220(D) mm (Portrait) Packed: Approximately 15Kg, 470(W) x 670(H) x 340(D)
Power Supply	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz

Similarities: MS35i2 (ML21035) employs the same tilt stand and back enclosure as those of predicate device MS33i2 (ML21033) (K112145).

Differences:

MS35i2 (ML21035) employs a different front bezel, LCD panel and power supply.

MS35i2 (ML21035) can be considered to have equivalent display performances to those of the predicate device MS33i2 (ML21033) (K112145) due to the following reasons:

a. The maximum display sizes (1536*6144 (Sub-pixel)) used for the both devices are same though the active area size (324.864mm (H) x 433.152mm (V)) for MS35i2 (ML21035) is larger than that for the predicate device (318.0mm (H) x 423.9mm (V)). The size difference between both devices will not affect the safety and effectiveness of MS35i2 (ML21035).

b. The DICOM calibrated luminance values of the both devices are the same (500 cd/m2) though the typical maximum luminance value (1700 cd/m2) is higher than that of the predicate device (1000 cd/m2). The higher luminance to be maintained constantly was realized by the employment of LED backlight deteriorating more slowly than conventional CCFL backlights.

c. The LED backlight was newly employed instead of CCFL backlight because it is mercury-free, consumes less power and deteriorates more slowly. We have not recognized any adverse effects of the LED backlight on the quality of displayed images. Refer to "Technical Data" where several image quality characteristics of the proposed device are compared with those of the predicate device.

d. The both devices display images in accordance with DICOM GSDF by default utilizing the factory calibrated display mode stored in lookup tables inside of them.

e. Both devices support Digital Visual Interface (DVI) and DisplayPort.

As for the maintenance, the same QC software is used for both devices. Both devices have Front Sensor to stabilize the luminance.

As for built-in sensors, both devices have 2 (two) kinds of common sensors, Front Sensor and Ambient Light Sensor. Front Sensor is related to the maintenance or calibration and Ambient Light Sensor is used to measure the ambient light by lx. Front sensor enables automatic grayscale calibration by measuring the luminance at the screen surface. Without Front sensor, the grayscale calibration process requires human intervention and the use of an external sensor. The accuracy data of the calibration with external sensors and that with Front Sensor is included in section 9 "Verification & Validation" in "Application".

The overall design of the MS35i2 (ML21035) was validated in accordance with internationally recognized Safety and EMC standards by third-party certifiers. Besides, JVC KENWOOD Corporation performed a range of system and performance tests to ensure that the MS35i2 (ML21035) performs in accordance with its specifications. None of the tests revealed behaviors inconsistent with the expected performance.

Display System Description

1. Active-Matrix Liquid-Crystal Displays (AMLCD) panel manufacturer, technologyScreen size and pixel pitch:
   Screen size: 433.152(H)mm x 324.864(V) mm at landscape display, 324.864(H)mm x 433.152(V)mm at portrait display, Pixel pitch: 0.0705mm(H) (sub-pixel pitch) x 0.2115(V) at landscape display, 0.2115mm(H) x 0.0705(V) (sub-pixel pitch) at portrait display
   - Communicating ports:
     Serial communication: USB (upstream x1, downstream x2)
2. Graphics card and software
   - Digital-to-Analog converters: speed and precision:
     Only Digital operation, Digital to Analog converters are not provided.
   - Software included: calibration, QC/QA (procedures with required frequencies and action limits):
     Totoku's calibration software called "Mediviser" optimizes the display's performance using DICOM GSDF gamma and luminance. Calibration is recommended quarterly.
   - On-screen GUI: On-screen GUI is not provided.
   - Panel user controls: power switch

Technical Specification

1. Measuring Equipment
2. Declared and actual (measured with test pattern in the screen) array size
3. Luminance response
   - max and min achievable luminance
   - max and min recommended (operational) luminance
   - intrinsic bit-depth of the panel
   - true output bit-depth by performing visual test with gradient test pattern
   - intrinsic luminance response at 256 digital values
   - conformance to a grayscale function (i.e., DICOM GSDF) at 256 digital values and angular dependence of such conformance
4. Angular Dependencies
   - angular dependency o_f luminance
5. Luminance uniformity:
   based on AAPM-TG18 4.4
6. Geometrical distortion:
   based on AAPM-TG18
7. Display reflectance:
   based on AAPM-TG18 4.2.4
8. Noise
   - pixel fill factor
   - noise power spectrum (weiner spectrum)
9. Veiling glare:
   based on AAPM-TG18 4.7.4
10. Chromaticity
    based on AAPM-TG18 4.8.4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 6, 2014

JVC KENWOOD CORPORATION
% Mr. Tsukasa Tashiro
General Manager
3-12, Moriya-Cho, Kanagawa-Ku
Yokohama-Shi, Kanagawa 221-0022
JAPAN

Re: K133686
Trade/Device Name: 21.3 inch (54 cm) inch Monochrome Digital Mammography LCD Monitor MS35i2 (ML21035)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 29, 2013
Received: December 2, 2013

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.

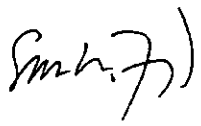
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133686

Device Name
MS35i2 (ML21035)

Indications for Use *(Describe)*

21.3 inch (54 cm) inch Monochrome Digital Mammography 3M pixel LCD Monitor with sub-pixel driving techniques enabling 9M sub-pixels to be driven independently. MS35i2 (ML21035) 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 and modalities including FFDM.

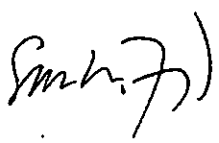
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."