



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

JVC KENWOOD CORPORATION
% Mr. Tsukasa Tashiro
Senior Manager
3-12 Moriya-cho, Kanagawa-ku
Yokohama-shi, Kanagawa, 221-0022
JAPAN

November 12, 2014

Re: K143076
Trade/Device Name: 20.1 inch (51 cm) Monochrome LCD Monitor ME205 (ML20205)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: October 24, 2014
Received: October 27, 2014

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 cursive script that reads "Robert A. Ochs". The signature is written in black ink and is positioned above the typed name of the signatory.

for

Janine M. Morris
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)

~~Not known~~

K143076

Device Name

ME205 (ML20205)

Indications for Use (Describe)

20.1 inch (51 cm) Monochrome 2M pixel LCD Monitor ME205 (ML20205) is intended to be used in displaying and viewing medical images for diagnosis by trained Medical practitioners. 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)

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)



510(k) SUMMARY

Submitted Information: JVC KENWOOD CORPORATION
3-12, MORIYA-CHO, KANAGAWA-KU,
YOKOHAMA-SHI, KANAGAWA, 221-0022 JAPAN

Contact Person: Tsukasa Tashiro, Senior Manager
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Date Prepared: October 24, 2014

Device Name: 20.1 inch (51 cm) Monochrome LCD Monitor ME205 (ML20205)

Common Name: ME205, ML20205

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

Predicate Device: 20.1 inch (51 cm) Monochrome LCD Monitor ME201 (MDL2006A)
(K021738)

Device Description: ME205 (ML20205) is a 20.1-inch (51 cm) Monochrome LCD monitor whose display resolution is 1600 x 1200 (landscape), 1200 x 1600 (portrait) supporting DVI-I (both digital and analog interface) and DisplayPort (digital interface).

Intended Use: 20.1 inch (51 cm) Monochrome 2M pixel LCD Monitor, ME205 (ML20205) is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners. It is not meant to be used in digital mammography.

Substantial Equivalence: ME205 (ML20205) shares the same technical characteristics, application and intended use with our predicate device ME201 (K021738).

JVC KENWOOD Corporation

Healthcare Business Operation, Professional Systems Segment
3-12, Moriya-cho, Kanagawa-ku,
Yokohama-shi, Kanagawa, 221-0022 Japan

Technical Specification

1. Luminance uniformity
[SPEC] Less than 30% based on AAPM-TG18 4.4. Refer to actual Luminance uniformity data
2. Pixel Defects / Fault
[SPEC] Class II or more. ISO13406-2
3. Artifacts
 - phase/clock issues flicker
 - miscellaneous including ringing, ghosting, image sticking[SPEC] By visible check, no flicker, ringing, ghosting and image sticking
4. Chromaticity Measurement of 5%, 50%, 95% Level
[SPEC] Refer to actual data.
5. Chromaticity
[SPEC] $\Delta(u', v') \leq 0.01$ measured at 80% Lmax based on AAPM-TG18 4.8.4
Refer to Chromaticity actual data
6. Power On Luminance Drift
[SPEC] Refer to actual data.

Substantial Equivalence Comparison

	ME201L (MDL2006A)	ME205 (ML20205)
510(k) Number	K021738	Not Known
Display Area	Horizontal: 408.0mm, Vertical: 306.0mm	Horizontal: 408.0mm, Vertical: 306.0mm
Pixel Pitch	0.255 mm x 0.255mm	0.255 mm x 0.255mm
Input Signal	Video signal-analog 0.7Vpp/ 75 Ω DVI-D digital video signal	DVI-I 29-pin connector, DisplayPort connector
Maximum Resolution	1600 x 1200 at landscape display	1200 x 1600 at portrait display 1600 x 1200 at landscape display
Scanning Frequency	Horizontal: 31 – 80kHz Vertical: 55 – 85Hz	Horizontal: 30 – 75kHz Vertical: 55 – 60Hz
Maximum Image Clock	162MHz	162MHz
Maximum Luminance	410 cd/m ² DICOM calibrated 700 cd/m ² typ. As LCD component	410 cd/m ² DICOM calibrated 1000 cd/m ² typ. As LCD component
Luminance Calibration (Optional)	Software Photo Sensor (optional): DTP92(X-Rite)	Software Photo Sensor (optional): X-Rite Chroma 5
Contrast Ratio	Typ. 1000:1	Typ. 1000:1
Serial Communication	RS-232C	USB
Safety Standards	Medical Safety: UL2601-1, CSA No. 601-1 EN60601-1	Medical Safety: ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1, FCC (Class B), MDD/CE, VCCI-B (Class B), ICES-003 (Class B)
Weight & Dimension	Net: 10.8kg 453(w) x 466(H) x 251(D) mm (landscape) 353(w) x 520(H) x 251(D) mm (portrait) Packed: 14kg 470(W) x 680(H) x 340(D) mm	Net: 9.6kg 453(w) x 462 – 523(H) x 220(D) mm (landscape) 353(w) x 512 – 573(H) x 220(D) mm (portrait) Packed: 12.5kg 470(w) x 675(H) x 347(D) mm
Power Supply	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz

Differences: ME205 (ML20205) employs a different LCD panel, power supply, and main board from the predicate device ME201L (K021738).

Similarities: ME205 (ML20205) employs the same front bezel and tilt stand as those employed on the predicate device ME201L (K021738). The back enclosures of both devices are similar to each other.

ME205 (ML20205) can be considered to have equivalent display performances to those of the predicate device ME201L (K021738) due to the following reasons:

- a. The active sizes (408.0mm x 306.0mm) and the maximum display resolution (1600 x 1200) used for the both devices are the same.
- b. The DICOM calibrated luminance values of the both devices are the same (410cd/m²). In regard to the maximum luminance, the value of the predicate device ME201L (K021738) is 700cd/m², whereas that of ME205 (ML20205) is set to a higher value of 700cd/m². Additionally ME205 (ML20205) realizes high luminance at constantly stable level by adopting LED backlight, which lasts longer than conventional CCFL backlights do.
- 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. The predicate device ME201L (K021738) supports DVI-D (digital interface) and D-Sub (analog interface), whereas ME205 (ML20205) supports DVI-I (both digital and analog interface) and DisplayPort (digital interface).

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

The overall design of the ME205 (ML20205) 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 ME205 (ML20205) performs in accordance with its specifications. None of the tests revealed behaviors inconsistent with the expected performance.

Conclusion

The 2M pixel Monochrome LCD Monitor, ME205 (ML20205) is 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 to those of the predicate device and other differences have been independently validated. Any differences between the devices do not affect safety or effectiveness.