



May 10, 2018

EIZO Corporation
% Hiroaki Hashimoto
Senior Manager
153 Shimokashiwano
Hakusan, Ishikawa 924-8566
JAPAN

Re: K180961

Trade/Device Name: RadiForce MX194
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: April 10, 2018
Received: April 12, 2018

Dear Hiroaki Hashimoto:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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

Robert Ochs, Ph.D.
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)

K180961

Device Name

RadiForce MX194

Indications for Use (Describe)

This Product is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for 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.

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
PRASStaff@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."



EIZO Corporation, 153 Shimokashiwano, Hakusan, Ishikawa
924-8566 Japan

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Name Hiroaki Hashimoto
Department Regulatory Compliance and Safety

Telephone +81 (76) 274-2468
Fax +81 (76) 274-2484
E-Mail hiroaki.hashimoto@eizo.com

510(k) Summary

1. Submitter

EIZO Corporation
153 Shimokashiwano, Hakusan,
Ishikawa 924-8566 Japan
Phone: +81 (76) 274-2468
Fax: +81 (76) 274-2484

Contact Person: Hiroaki Hashimoto
Date of Prepared: April 10th, 2018

2. Device

- Name of Device: RadiForce MX194
- Common or Usual Name: 48.1 cm (19.0 inch) class Color LCD Monitor
- Classification Name: Display, Diagnostic Radiology (21 CFR 892.2050)
- Regulatory Class: II
- Product Code: PGY

3. Predicate Device

EIZO Corporation
RadiForce MX215 (K131090)

4. Device Description

RadiForce MX194 is a color LCD monitor for viewing medical images other than those of mammography. The color panel employs Vertical Alignment (VA) technology allowing high contrast ratio and the matrix size (or resolution) is 1,280 x 1,024 pixels (1MP) with a pixel pitch of 0.294 mm.

Since factory calibrated display modes, each of which is characterized by a specific tone curve (including DICOM GSDF), a specific luminance range and a specific color temperature, are stored in lookup tables within the monitor, the tone curve is e.g. DICOM compliant regardless of the display controller used.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including the RadiForce MX194 based on the QC standards and guidelines and is capable of quantitative tests and visual tests defined by them. The RadiCS and its subset, RadiCS LE, are included in this 510(k) submission as an accessory to the RadiForce MX194.

5. Indications for use

This Product is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

6. Comparison of Technological Characteristics with the predicate device

The comparison table below enumerates information derived from the product brochure of the each device and different technological characteristics are discussed in it:

Attributes	Proposed Device: RadiForce MX194	Predicate Device: RadiForce MX215
Display Technology		
	TFT Color LCD Panel (VA)	TFT Color LCD Panel (IPS)
Screen size		
	48.1cm / 19.0" Aspect ratio: 5 : 4	54cm / 21.3" Aspect ratio: 3 : 4
Backlight type		
	LED	LED
Frame rate and refresh rate		
Digital Scanning Frequency (H / V)	31 - 64 kHz / 59 - 61 Hz	31 - 100 kHz / 59 - 61 Hz
Analog Scanning Frequency (H / V)	24.8 - 80 kHz / 50 - 75 Hz	26 - 100 kHz / 49 - 76 Hz
Display Interface		
Input video signals	DVI-D x 1, DisplayPort x 1, D-Sub mini 15 pin x 1	DVI-I x 1, DisplayPort x 1
Video bandwidth		
	DVI : 108MHz DisplayPort : 108MHz Analog : 135MHz	DVI : 164.5MHz DisplayPort : 164.5MHz Analog : 164.5MHz
Ambient light sensing		
Ambient light sensor	Yes	Yes
Luminance calibration tools		
	Integrated optical sensor External optical sensor Calibration software: RadiCS	Integrated optical sensor External optical sensor Calibration software: RadiCS
Quality-control procedures		
	Software: RadiCS	Software: RadiCS

It is clear that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the MX194.

7. Performance Testing

The bench tests below were performed on the RadiForce MX194 following the instructions in “*Guidance for Industry and FDA Staff: Display Devices for Diagnostic Radiology*” issued on October 2, 2017:

- Measurement of spatial resolution expressed as modulation transfer function (MTF)
- The maximum number allowed for each type of pixel defects/faults
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in TG18 guideline
- Measurement of temporal response
- Measurement of Luminance
- Verification of the conformance to DICOM GSDF as specified in *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline)
- Measurement of Color tracking

The test results showed that the RadiForce MX194 has display characteristics equivalent to those of the predicate device, RadiForce MX215.

Besides, the display characteristics of the RadiForce MX194 meet the pre-defined criteria when criteria are set.

No animal or clinical testing was performed on the RadiForce MX194.

8. Conclusion

The RadiForce MX194 was determined to be substantially equivalent to the predicate device due to the following reasons:

- The stated intended use is substantially the same as that of the predicate device.
- It was confirmed that the technological characteristics differences from those of the predicate device do not affect the safety or the effectiveness.
- The bench tests demonstrated that the display characteristics are equivalent to those of the predicate device.