May 23, 2025

EIZO Corporation
Hiroaki Hashimoto
Senior Manager of Regulatory Compliance and Safety Department
153 Shimokashiwano
Hakusan, Ishikawa 924-8566
Japan

Re: K242545
Trade/Device Name: RadiForce MX317W-PA
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: PZZ
Dated: August 27, 2024
Received: August 27, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shyam Kalavar -S

Shyam Kalavar
Deputy Branch Chief
Division of Molecular Genetics and Pathology
OHT7: Office of In Vitro Diagnostics
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)*
K242545

Device Name
RadiForce MX317W-PA

Indications for Use *(Describe)*
RadiForce MX317W-PA is intended for in vitro diagnostic use to display digital images of histopathology slides acquired from IVD-labeled whole-slide imaging scanners and viewed using IVD-labeled digital pathology image viewing software that have been validated for use with this device.

RadiForce MX317W-PA is an aid to the pathologist and is used for review and interpretation of histopathology slides for the purposes of primary diagnosis. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using this product. The display is not intended for use with digital images from frozen section, cytology, or non- formalin-fixed, paraffin embedded (non-FFPE) hematopathology specimens.

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.

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510(k) Summary
K242545

1. Submitter

EIZO Corporation
153 Shimokashiwano, Hakusan,
Ishikawa 924-8566 Japan
Phone: +81 (76) 274-2468
Contact Person: Hiroaki Hashimoto
Date of Prepared: May 19, 2025

2. Device

- Name of Device: RadiForce MX317W-PA
- Common or Usual Name: 30.5 inch (77.5 cm) Color LCD Monitor
- Classification Name: Whole Slide Imaging System (21 CFR 864.3700)
- Regulatory Class: II
- Product Code: PZZ

3. Predicate Device

- Name of Device: MDPC-8127 (K203364)
- Common or Usual Name: Digital Pathology Display
- Classification Name: Whole Slide Imaging System (21 CFR 864.3700)
- Regulatory Class: II
- Product Code: PZZ

4. Device Description

RadiForce MX317W-PA is a color LCD monitor for viewing digital images of histopathology slides. The color LCD panel employs in-plane switching (IPS) technology allowing wide viewing angles and the matrix size is 4,096 x 2,160 pixels (8MP) with a pixel pitch of 0.1674 mm.

Since factory calibrated display modes, each of which is characterized by a specific tone curve, a specific luminance range and a specific color temperature, are stored in lookup tables within the monitor. This helps ensure tone curves even if a display controller or workstation must be replaced or serviced.

"Patho" is for intended digital pathology use mode.

5. Indications for use

RadiForce MX317W-PA is intended for in vitro diagnostic use to display digital images of histopathology slides acquired from IVD-labeled whole-slide imaging scanners and viewed using IVD-labeled digital pathology image viewing software that have been validated for use with this device. RadiForce MX317W-PA is an aid to the pathologist and is used for review and interpretation of histopathology slides for the purposes of primary diagnosis. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using this product. The display is not intended for use with digital images from frozen section, cytology, or non-formalin-fixed, paraffin embedded (non-FFPE) hematopathology specimens.

6. Comparison of Technological Characteristics with the predicate device

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

Attributes	Proposed Device: RadiForce MX317W-PA	Predicate Device: Barco MDPC-8127
Indications for Use		
	RadiForce MX317W-PA is intended for in vitro diagnostic use to display digital images of histopathology slides acquired from IVD-labeled whole-slide imaging scanners and viewed using IVD-labeled digital pathology image viewing software that have been validated for use with this device. RadiForce MX317W-PA is an aid to the pathologist and is used for review and interpretation of histopathology slides for the purposes of primary diagnosis. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using this product. The display is not intended for use with digital images from frozen section, cytology, or non-formalin-fixed, paraffin embedded (non-FFPE) hematopathology specimens.	The Barco MDPC-8127 device is intended for in vitro diagnostic use to display digital images of histopathology slides acquired from IVD-labeled whole-slide imaging scanners and viewed using IVD-labeled digital pathology image viewing software that have been validated for use with this device. It is an aid to the pathologist to review and interpret digital images of histopathology slides for primary diagnosis. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using the MDPC-8127. The display is not intended for use with digital images from frozen section, cytology, or non-formalin-fixed, paraffin embedded (non-FFPE) hematopathology specimens.
Technological characteristics of the display device		
	TFT Color LCD Panel (IPS)	IPS
Physical size of the viewable area and aspect ratio		
	77.5cm / 30.5" Aspect ratio: 17 : 9	68.4cm / 27" Aspect ratio: 16 : 9
Backlight type and properties including temporal, spatial, and spectral characteristics		
	LED	LED
Frame rate and refresh rate		
Frame rate	60 Hz	120Hz
Pixel array, pitch, pixel aperture ratio and subpixel matrix scheme		
Pixel pitch	0.1674 mm x 0.1674 mm	0.155 mm
Subpixel pattern	RGB Vertical Stripe	RBG vertical stripe
Pixel aperture ratio	0.571	0.502

Subpixel driving to improve grayscale resolution (e.g., spatial and temporal dithering)		
Independent Subpixel drive	OFF	OFF
Dithering	LCD Specification: True 10bit color Multi-gradation is achieved by 3-bit FRC signal processing inside the monitor	-
Display Interface		
Input video signals	USB Type-C (DisplayPort Alt Mode) x 1, DisplayPort x 2, HDMI x 1	DisplayPort x 2
Output video signals	USB Type-C (daisy chain) x 1	None
Ambient light adaptation including the ambient light sensing method, instrumentation, and software tool description		
Ambient light sensor	Photo Diode Position: In the upper bezel of the screen Software tool: RadiCS	Yes
Touch screen technology including method, functionality, and any calibration or periodical re-tuning requirements		
	N/A	N/A
Color calibration tools (sensor hardware and associated software), color profile, and method for color management		
	Integrated optical sensor External optical sensor Calibration software: RadiCS	Front sensor: I-Guard Calibration software: QAWeb Enterprise
Frequency and nature of quality-control tests to be performed by the user and/or the physicist with associated action limits.		
	Software: RadiCS AAPM On-line Report No. 03:2005 compliant	Software: QAWeb Enterprise

The technological characteristics differences discussed above do not affect the safety and the effectiveness of the MX317W-PA.

7. Performance Testing

The bench tests below were performed on the RadiForce MX317W-PA following the instructions in *"Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices"* issued on April 20, 2016:

- User controls: Modes and settings of the display undergoing testing.
- Spatial resolution
- Pixel defects
- Artifacts
- Temporal response
- Maximum and minimum luminance
- Grayscale
- Luminance uniformity and Mura test
- Stability of luminance and chromaticity response
- Bidirectional reflection distribution function
- Gray Tracking
- Color scale
- Color gamut volume

The test results showed that the RadiForce MX317W-PA has display characteristics equivalent to those of the predicate device, Barco MDPC-8127.

Besides, the display characteristics of the RadiForce MX317W-PA meet the pre-defined criteria when criteria are set.

No animal or clinical testing was performed on the RadiForce MX317W-PA.

8. Conclusion

The RadiForce MX317W-PA 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.