



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

I Background Information:

A 510(k) Number

K242545

B Applicant

EIZO Corporation

C Proprietary and Established Names

RadiForce MX317W-PA

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PZZ	Class II	21 CFR 864.3700 - Whole Slide Imaging System	PA - Pathology

II Review Summary:

A Purpose for Submission:

New digital pathology display

B Type of Test:

Digital Pathology Display

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

RadiForce MX317W-PA is a color LCD monitor for viewing digital images of histopathology slides. The color panel employs in-plane switching (IPS) technology allowing wide viewing angles. The display characteristics and specifications are provided in the following table.

Display Characteristics

Technological characteristics of the display device	
	TFT Color LCD Panel (IPS)
Physical size of the viewable area and aspect ratio	
	77.5cm / 30.5" Aspect ratio: 17 : 9
Backlight type and properties including temporal, spatial, and spectral characteristics	
	LED
Frame rate and refresh rate	
Digital Scanning Frequency (H / V)	USB Type-C: 31 - 134 kHz / 59 - 61 Hz DisplayPort: 31 - 134 kHz / 59 - 61 Hz HDMI: 31 - 136 kHz / 59 - 61 Hz
Pixel array, pitch, pixel aperture ratio and subpixel matrix scheme	
Pixel pitch	0.1674 mm x 0.1674 mm
Subpixel pattern	RGB Vertical Stripe
Pixel aperture ratio	0.571

Subpixel driving to improve grayscale resolution (e.g., spatial and temporal dithering)	
Independent Subpixel drive	OFF
Dithering	LCD Specification: True 10-bit 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
Output video signals	USB Type-C (daisy chain) x 1
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
Color calibration tools (sensor hardware and associated software), color profile, and method for color management	
	Integrated optical sensor or external optical sensor controlled by the RadiCS software

V Substantial Equivalence Information:

A Predicate Device Name(s):

Barco MDPC-8127

B Predicate 510(k) Number(s):

K203364

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K242545</u>	<u>K203364</u>
Device Trade Name	RadiForce MX317W-PA	Barco MDPC-8127
General Device Characteristic Similarities		
Intended Use/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	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

Device & Predicate Device(s):	<u>K242545</u>	<u>K203364</u>
	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.	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.
Backlight type and properties including temporal, spatial, and spectral characteristics	LED	LED
Subpixel pattern	RGB Vertical Stripe	RGB Vertical Stripe
Independent Subpixel drive	Off	Off
Technological characteristics of the display device	TFT Color In-Plane Switching (IPS) Liquid Crystal Display (LCD)	Color In-Plane Switching (IPS) Liquid Crystal Display (LCD)
General Device Characteristic Differences		
Physical size of the viewable area and aspect ratio	77.5 cm / 30.5" Aspect ratio: 17:9	68.4 cm / 27" Aspect ratio: 16:9
Pixel aperture ratio	0.571	0.502

VI Standards/Guidance Documents Referenced:

1. FDA Guidance document: Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices. Guidance for Industry and Food and Drug Administration Staff. April 20, 2016 (TPA Guidance).
2. ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021].
3. ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021].
4. IEC TR 60601-4-2 Edition 1.0 2016-05.
5. IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
Not applicable.
2. Linearity:
Not applicable.
3. Analytical Specificity/Interference:
Not applicable.
4. Accuracy (Instrument):
Not applicable.
5. Carry-Over:
Not applicable.

B Other Supportive Instrument Performance Characteristics Data:

Technical performance testing for RadiForce MX317W-PA display was performed according to the TPA guidance (section IV(A)(11)(b)). Bench testing included assessment of the following performance characteristics:

Test	Test Method	Results	
		MX317W-PA	MDPC-8127
User controls	N/A	Luminance target, maximum: 370 cd/m ² Display function: sRGB White point: 6500K Color space: sRGB	Luminance target, maximum: 450 cd/m ² Display function: sRGB White point: 6500K Color space: sRGB

Test	Test Method	Results	
		MX317W-PA	MDPC-8127
		Mode: Patho	
Spatial resolution	The spatial resolution or Modulation Transfer Function (MTF) is measured and calculated by using the method proposed in “Novel MTF Measurement Method for Medical Image Viewers Using a Bar Pattern Image” by Katsuhiro Ichikawa et al. in Proceedings of SPIE Vol. 5029, pp.624-631 (2003)".	Both horizontal and vertical MTFs are greater than 92.7% at Nyquist frequency	Both horizontal and vertical MTFs are greater than 82.7% at Nyquist frequency
Pixel defects	- “Dot” corresponds to a sub-pixel; an entire pixel consists of three sub-pixels. - “Bright Dot” and “Tiny Bright Dot” are distinguished by the brightness level, e.g., whether visible or not on the gray background whose DDL is equal to 96. - Defects are referred to as “Tiny Bright Dot” since the darker “Bright Dots” are mostly due to foreign material and the sizes tend to be smaller than those of the brighter “Bright Dots”. - “Black Dot”: A dot recognized by human eyes as a black dot is counted as “Black Dot” regardless of the brightness and the size.	Maximum number allowed: Bright Dots: 0 Tiny Bright Dots: 16 Black Dots: 15	Maximum number allowed - Total: 5
Artifacts	Visual artifacts including ringing, ghosting and image sticking were checked with the TG18 QC pattern	No visual artifacts were seen.	No visual artifacts were seen.

Test	Test Method	Results	
		MX317W-PA	MDPC-8127
Temporal response	“Liquid Crystal Response Time (LCRT)” in the maximum luminance was measured. LCRT is standardized under International Committee for Display Metrology (ICDM) “Information Display Measurements Standard (IDMS)” Chapter 10.2.	Average: 17.6 ms Gray to Gray: 19.2 ms Maximum: 27.8 ms Minimum: 9.9 ms 0→255→0: 25.5 ms	Average: 5.0 ms Gray to Gray: 5.1 ms Maximum: 7.6 ms Minimum: 3.1 ms 0→255→0: 10.1 ms
Maximum and minimum luminance	Maximum and minimum luminance were measured (cd/m ²).	Achievable -Max.: 547.5 -Min.: 0.289 Recommended -Max.: 370.5 -Min.: 0.398 Targeted -Max.: 370.0 -Min.: 0.40	Achievable -Max.: 678.6 -Min.: 0.633 Recommended -Max.: 445.0 -Min.: 0.457 Targeted -Max.: 450.0 -Min.: -
Grayscale	Measure the luminance of 18 DDLs at the screen center	Maximum Error Rate: 0.73%	Maximum Error Rate: 1.58%
Luminance uniformity and Mura test	The luminance non-uniformity was assessed in accordance with the following extract from the TG18 guideline.	DDL 204: 2.1%	DDL 204: 5.5%
Stability of luminance and chromaticity response	To evaluate the white (DDL=255) luminance stability over time	Deviation from target luminance (370 cd/m ²): 0.79% Variations for luminance and chromaticity: < 2.29% deviation	Deviation from target luminance (450 cd/m ²): - 2.66% Variations for luminance and chromaticity: < 5.12% deviation
Reflection: Specular & Haze Components	The reflective property of the display screen was evaluated by measuring the specular reflection while varying the sizes of light source using the method proposed in “Effects of the Reflection Properties of Liquid-Crystal Displays on Subjective Ratings of Disturbing Reflected Glare”	3°: 0.541 5°: 1.264 7°: 2.046 10°: 3.123 15°: 4.266	3°: 0.603 5°: 1.429 7°: 2.277 10°: 3.353 15°: 4.462

Test	Test Method	Results	
		MX317W-PA	MDPC-8127
	by Satoru KUBOTA et al. J. Lights & Vis. Env. Vol 21, No.1, 1997.		
Reflection: Diffuse Reflection Coefficient	The diffuse reflection coefficient was measured in a dark-room environment using a sphere and a spectroradiometer	0.0044	0.0060
Gray tracking	The CIE xyY values of gray levels (0-255 DDLs) at the screen center measured	0.00065 $\Delta u'v'$ White point at D65: 0.00038 $\Delta u'v'$	0.063 $\Delta u'v'$ White point at D65: 0.00076 $\Delta u'v'$
Color scale	The color patches specified by the ISO standard were measured. - ISO 12646: All combinations of 0, 63, 12, 191, 255/255 gradations for each of RGB + Gray 32, 98, 131, 157, 178, 196, 213, 228, 242/255 for a total of 134 patches. - ISO 14861: 318 patches defined in Annex A.	134 patches: Ave.: 0.17 ΔE_{00} Max.: 0.74 ΔE_{00} 138 patches: Ave.: 0.20 ΔE_{00} Max.: 0.86 ΔE_{00}	134 patches: Ave.: 0.41 ΔE_{00} Max.: 1.36 ΔE_{00} 138 patches: Ave.: 0.54 ΔE_{00} Max.: 1.76 ΔE_{00}
Color gamut volume	The chromaticity at the center of the screen was measured to determine the coverage of the sRGB color gamut.	sRGB cover ratio: 99.2%	sRGB cover ratio: 99.0%

VIII Proposed Labeling:

The labeling is sufficient, and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable, and the special controls for this device type, as applicable.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.