



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K233119

B Applicant

Shenzhen Beacon Display Technology Co., Ltd.

C Proprietary and Established Names

8MP Color LCD Displays C811W, C811WT, PA27 and PA27T

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 displays as follows:

8MP Color LCD Display C811W

8MP Color LCD Display C811WT

8MP Color LCD Display PA27

8MP Color LCD Display PA27T

B Type of Test:

Digital pathology display monitors.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

8MP Color LCD Displays C811W, C811WT, PA27 and PA27T are 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. They are 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 8MP Color LCD Displays C811W, C811WT, PA27 and PA27T. The displays are 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:**

The C811WT, C811WT, PA27 and PA27T are 8MP Color LCD displays, specifically intended for review and interpretation of surgical pathology slides from IVD-labeled whole-slide imaging scanners that have been validated for use with the display. The displays are equipped with a 27-inch color LCD panel with a fine pixel pitch and LED backlight panels. The built-in brightness stabilization control circuits enable the brightness of these displays are stable throughout the product life. Displays models C811WT and PA27T have capacitive touch screen and models C811W, PA27 do not have a capacitive touch screen.

V Substantial Equivalence Information:**A Predicate Device Name(s):**

Leica Aperio GT 450 DX

B Predicate 510(k) Number(s):

K232202

C Comparison with Predicate:

Device & Predicate Device(s):	<u>Device K233119</u>	<u>Predicate K232202</u>
Device Trade Name	Shenzhen Beacon 8MP Color LCD displays C811WT, PA27T, C811W and PA27	Aperio GT 450 DX (Barco MDPC-8127 display component)
General Device Characteristic Similarities		
Screen size	684 mm (27")	684 mm (27")
Backlight type	LED	LED
Color Calibration	sRGB	sRGB
Contrast Ratio (typical)	1000:1	1000:1
General Device Characteristic Differences		
Display Technology	TFT Color LCD Panel (AHVA)	TFT Color LCD Panel (IPS)
Resolution	3840 x 2160 @ 60 Hz (16:9 aspect ratio)	3840 x 2160 @ 120 Hz (16:9 aspect ratio)
Pixel pitch	0.15525 x 0.15525 mm	0.155 x 0.155 mm
Calibrated luminance	500 cd/m ²	450 cd/m ²
Display Interface	DVI-D x 1 HDMI x 1 DisplayPort x 1	DisplayPort x 2
Ambient light sensor	N/A	Yes
Touch screen technology	Capacitive touch screen	N/A
Calibration tools	Front sensor; Calibration Feedback system	Front sensor; QAWeb

General Technological Characteristics Comparison of C811WT and PA27T

Attributes	Proposed Device 8MP Color LCD Monitor (C811WT, PA27T)	Predicate Device 8MP Color LCD Monitor Barco MDPC-8127
Display Technology	TFT Color LCD Panel (AHVA)	TFT Color LCD Panel (IPS)
Screen size	684 mm (27")	684 mm (27")
Resolution	3840 x 2160 @ 60 Hz (16:9 aspect ratio)	3840 x 2160 @ 120 Hz (16:9 aspect ratio)
Pixel pitch	0.15525 x 0.15525 mm	0.155 x 0.155 mm
Backlight type	LED	LED
Color Calibration	sRGB	sRGB
Calibrated luminance	500 cd/m ²	450 cd/m ²
Contrast Ratio (typical)	1000:1	1000:1
Display Interface	DVI-D x 1, HDMI x 1, DisplayPort x 1	DisplayPort x 2
Ambient light sensor	N/A	Yes
Touch screen technology	Capacitive touch screen	N/A
Calibration tools	Front sensor; Calibration Feedback System	Front sensor QAWeb

General Technological Characteristics Comparison of C811W and PA27

Attributes	Proposed Device 8MP Color LCD Monitor (C811W, PA27)	Predicate Device 8MP Color LCD Monitor Barco MDPC-8127
Display Technology	TFT Color LCD Panel (AHVA)	TFT Color LCD Panel (IPS)
Screen size	684 mm (27")	684 mm (27")
Resolution	3840 x 2160 @ 60 Hz (16:9 aspect ratio)	3840 x 2160 @ 120 Hz (16:9 aspect ratio)
Pixel pitch	0.15525 x 0.15525 mm	0.155 x 0.155 mm

Backlight type	LED	LED
Color Calibration	sRGB	sRGB
Calibrated luminance	500 cd/m ²	450 cd/m ²
Contrast Ratio (typical)	1000:1	1000:1
Display Interface	DVI-D x 1, HDMI x 1, DisplayPort x 1	DisplayPort x 2
Ambient light sensor	N/A	Yes
Touch screen technology	N/A	N/A
Calibration tools	Front sensor; Calibration Feedback System	Front sensor QAWeb

VI Standards/Guidance Documents Referenced:

- ANSI AAMI, ES60601-1:2005/R2012&A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
- IEC, 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
- AAPM, TG18 Assessment of Display Performance for Medical Imaging System, 2005
- IEC, TR 60601-4-2 Edition 1.0 2016-05
- ISO, 14971 Third Edition 2019-12
- IEC, 62563-1 Edition 1.2 2021-07
- ICDM, IDMS v1.03
- 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 the displays was performed as specified in the Tables below:

Table: C811W, C811WT, PA27 and PA27T Test Results

Test	Test Method/ Applicable Standards	C811W	C811WT	PA27	PA27T
1.User controls	Modified-Performance Modes, IDMS 1.03, Section 2.1	Luminance target, Maximum: 500 cd/m ² Display function: sRGB White point: D65 (6500K) Color space: sRGB 30 minutes of warm-up time	Luminance target, Maximum: 500 cd/m ² Display function: sRGB White point: D65 (500K) Color space: sRGB 30 minutes of warm-up time	Luminance target, Maximum: 500 cd/m ² Display function: sRGB White point: D65 (6500K) Color space: sRGB 30 minutes of warm-up time	Luminance target, Maximum: 500 cd/m ² Display function: sRGB White point: D65 (6500K) Color space: sRGB 30 minutes of warm-up time
2.Spatial resolution	Effective Resolution, IDMS 1.03, Section 7.7	Vertical and Horizontal MTFs are 0.861 and 0.862 at Nyquist frequency	Vertical and Horizontal MTFs are 0.877 and 0.885 at Nyquist frequency	Vertical and Horizontal MTFs are 0.861 and 0.862 at Nyquist frequency	Vertical and Horizontal MTFs are 0.877 and 0.885 at Nyquist frequency
3.Pixel defects (count and map)	Defective Pixels, IDMS 1.03, Section 7.6	Total number of bright and dark pixels <= 5	Total number of bright and dark pixels <= 5	Total number of bright and dark pixels <= 5	Total number of bright and dark pixels <= 5
4. Artifacts	Artifacts and Irregularities, IDMS 1.03, Section 10.4	Deviation <0.54%	Deviation <0.62%	Deviation <0.34%	Deviation <0.68%
5. Temporal response	Gray-to-Gray Response Time, IDMS 1.03, Section 10.2.3	Tmax: 20.87ms Tmin: 9.88ms	Tmax: 20.09ms Tmin: 3.84ms	Tmax: 22.87ms Tmin: 6.11ms	Tmax: 22.09ms Tmin: 3.56ms
6. Maximum, minimum luminance and calibrated luminance	Vantage-Point Suite of Measurement, IDMS 1.03, Section 2.4	Maximum: 523.6cd/m ² Minimum: 0.501cd/m ²	Maximum: 502.9cd/m ² Minimum: 0.4805cd/m ²	Maximum: 510cd/m ² Minimum: 0.499cd/m ²	Maximum: 502.6cd/m ² Minimum: 0.515cd/m ²
7. Grayscale	Grayscale, IDMS 1.03, Section 6.1	Maximum deviation: 5.94 %	Maximum deviation: 5.33 %	Maximum deviation: 5.52%	Maximum deviation: 6.07 %

8. Luminance uniformity and Mura test	Sampled Vantage-Point Uniformity, IDMS 1.03, Section 8.1.2	11.16% non-uniformity on 100% video level	6.89% non-uniformity on 100% video level	9% non-uniformity on 100% video level	9.26% non-uniformity on 100% video level
9. Stability of luminance and chromaticity response with temperature and lifetime	Warm-up time, IDMS 1.03, Section 10.1	Deviation from target luminance (500 cd/m ²): 0.48% Variations for chromaticity: < 0.55%	Deviation from target luminance (500 cd/m ²): 0.66% Variations for luminance and chromaticity: < 0.64% deviation	Deviation from target luminance (500 cd/m ²): 0.66%, Variations for chromaticity: < 0.3%	Deviation from target luminance (500 cd/m ²): 0.63% Variations for luminance and chromaticity: < 0.7% deviation
10. Bidirectional reflection distribution function	Diagnostic: Characterizing Hemisphere Uniformity, IDMS 1.03, Section 11.12	Specular reflection coefficient: 4.4%, Diffuse reflection coefficient: 0.92%	Specular reflection coefficient: 4.19%, Diffuse reflection coefficient: 0.8%	Specular reflection coefficient: 4.4%, Diffuse reflection coefficient: 0.92%	Specular reflection coefficient: 4.19%, Diffuse reflection coefficient: 0.8%
11. Gray Tracking	Gray-scale Color Changes IDMS v1.03, Section 6.15	0.0006 Δu^*v^*	0.0016 Δu^*v^*	0.0006 Δu^*v^*	0.0014 Δu^*v^*
12. Color scale	Gray- and Color-Scale Measurement and 5.4 Color-Signal White, IDMS 1.03, Section 6	Maximum color error: <2 ΔE Average color error: <1 ΔE	Maximum color error: <2 ΔE Average color error: <1 ΔE	Maximum color error: <3 ΔE Average color error: <2 ΔE	Maximum color error: <3 ΔE Average color error: <2 ΔE
13. Color gamut volume	Volume-Color-Reproduction Capability, IDMS 1.03, Section 5.18	2D color gamut overlapped with sRGB: 99.5%	2D color gamut overlapped with sRGB: 99.6%	2D color gamut overlapped with sRGB: 98.7%	2D color gamut overlapped with sRGB: 99.6%

System-level test was also performed to test the displays with the Leica GT450DX system by displaying a test target and multiple tissue sample images. The results were acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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