



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

**I Background Information:**

**A 510(k) Number**

K203364

**B Applicant**

Barco NV

**C Proprietary and Established Names**

MDPC-8127

**D Regulatory Information**

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

**II Submission/Device Overview:**

**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:

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.

## C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

## IV Device/System Characteristics:

### A Device Description:

The Barco MDPC-8127 is a medical, color-calibrated display, specifically intended for review and interpretation of digital images of surgical pathology slides from IVD-labeled whole-slide imaging scanners and digital pathology image viewing software. The MDPC-8127 consists of a high-resolution 27-inch color LCD-panel and can be calibrated to the sRGB color gamut or other broader color spaces. The display uses built-in techniques to ensure constant accuracy over time. The display characteristics and specifications are provided in the Table below.

<b>Display Characteristics</b>	
<b>Screen technology</b>	IPS LCD with LED backlighting
<b>Active screen size (diagonal)</b>	684 mm (27")
<b>Active screen size (H x V)</b>	569 x 335 mm (22.4 x 13.2")
<b>Aspect ratio (H:V)</b>	16:9
<b>Resolution</b>	8MP (3840 x 2160 pixels @ 120 Hz)
<b>Pixel pitch</b>	0.155 mm
<b>Color imaging</b>	Yes
<b>Gray imaging</b>	Yes
<b>Color depth</b>	30 bit (1.07 billion possible colors)
<b>Viewing angle (H, V)</b>	178°
<b>Screen surface treatment</b>	Anti-Glare coating
<b>Uniformity Technology</b>	PPU

<b>Display Characteristics</b>	
<b>Color calibration</b>	sRGB, DICOM GSDF,
<b>Color gamut NTSC</b>	115% (typical)
<b>Color gamut sRGB</b>	132% (typical), 137.1% (measured)
<b>Color gamut DCI-P3</b>	105% (typical)
<b>Ambient light presets</b>	Yes, reading room selection
<b>Ambient light sensor</b>	Yes
<b>Front sensor</b>	Yes, I-Guard
<b>Maximum luminance (panel typical)</b>	850 cd/m <sup>2</sup>
<b>Calibrated luminance</b>	450 cd/m <sup>2</sup>
<b>Contrast ratio (panel typical)</b>	1000:1
<b>sRGB Delta E2000 (typical)</b>	< 1 (average) < 3 (maximum)
<b>Response time [(Tr + Tf)/2] (typical)</b>	8 ms (typical), 5.01 ms (measured)
<b>Housing color</b>	Black / White
<b>Video input signals</b>	2x DisplayPort 1.2
<b>USB ports</b>	1x USB 2.0 upstream (endpoint) 2x USB 2.0 downstream
<b>Power rating</b>	100-240 Vac, 50/60 Hz, 3.6-1.6 A
<b>Power consumption</b>	75 W (nominal) @ calibrated luminance of 450 cd/m <sup>2</sup> < 0.5 W (hibernate) < 0.5 W (standby)

## **B Instrument Description Information:**

1. Instrument Name:

MDPC-8127

2. Specimen Identification:

The FFPE tissue specimen is identified on the scanned images by patient-specific barcodes and/or patient identifying information present on the glass slides.

3. Specimen Sampling and Handling:

Specimen sampling, which includes FFPE tissues, is performed by clinicians. Biopsy specimens are processed and FFPE slides are scanned by trained healthcare professionals to generate a digital image.

4. Calibration:

Calibrated color spaces: DICOM GSDF and sRGB

5. Quality Control:

Image quality is checked by the user for acceptability. In addition, quality checks for the display are initiated by the QAWeb quality assurance software and performed as a background activity.

**V Substantial Equivalence Information:**

**A Predicate Device Name(s):**

Philips IntelliSite Pathology Solution

**B Predicate 510(k) Number(s):**

K192259

**C Comparison with Predicate:**

	<b>Device</b> K203364	<b>Predicate</b> K192259
Device Trade Name	Barco MDPC-8127	Philips Intellisite Pathology Solution MMPC-4227F1 (PP27QHD)
<b>Device Characteristics - Similarities</b>		
Screen Technology	In-Plane Switching (IPS) Liquid Crystal Display (LCD)	Same
Display Calibration	Standard Red Green Blue (sRGB), Digital Imaging and Communication in Medicine (DICOM)	Same
Aspect ratio (H:V)	16:9	Same
<b>Device Characteristics - Differences</b>		
Resolution	8MP (3840 x 2160 pixels)	3.6MP (2560 x 1440 pixels)

Uniformity Technology	Color Per Pixel Uniformity (PPU)	None
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## 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: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
3. IEC 62304 Edition 1.1 2015-06 Medical Device Software - Software Life Cycle Processes
4. ISO 15223-1 Third Edition 2016- 11-01 Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements
5. ISO 14971 Second edition 2007-03-01(5-40) Medical devices - application of risk management to medical devices.

## 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 Barco MDPC-8127 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	
		MDPC-8127	Predicate device
User controls	Out-of-the-box settings	Luminance target, maximum: 450 cd/m <sup>2</sup> Display function: sRGB White point: 6500K Color space: sRGB 10 minutes of warm-up time	Luminance target, maximum: 350 cd/m <sup>2</sup> Display function: sRGB White point: 6500K Color space: sRGB 10 minutes of warm-up time
Spatial resolution	Roehrig, Hans, et al. "In-field evaluation of the modulation transfer function of electronic display devices." <i>Medical Imaging 2004: Visualization, Image-Guided Procedures, and Display</i> . Vol. 5367. International Society for Optics and Photonics, 2004	Both horizontal and vertical MTFs are greater than 85% at Nyquist frequency	Both horizontal and vertical MTFs are greater than 75% at Nyquist frequency
Pixel defects	7.6 Defective Pixels, IDMS v1.03b	Total number of bright and dark pixels <= 5 with a minimum distance greater than 15 mm.	Total number of bright and dark pixels <= 3 within a circle of 10 mm. diameter
Artifacts	Image retention after 1 hour	< 0.65%	< 0.65%
Temporal response	10.2.3 Gray-to-Gray Response Time, IDMS v1.03b	The response time ranges from 3.1 ms to 6.2 ms with an average of 5.01 ms.	The response time is maximum 15 ms and typical 8 ms.
Maximum and minimum luminance	5 Fundamental Measurements, IDMS v1.03b	The maximum and minimum achievable luminance values are 678.6 and 0.633 cd/m <sup>2</sup> , respectively. The calibrated luminance target is 450 cd/m <sup>2</sup> . The contrast ratio is greater than 1000:1.	The maximum and minimum achievable luminance values are 550 and 0.3 cd/m <sup>2</sup> , respectively. The calibrated luminance target is 350 cd/m <sup>2</sup> . The contrast ratio is 1000:1.
Grayscale	Contrast response deviation, AAPM TG-18	Maximum error calculated = 1.4%	Maximum error calculated = 2.1%
Luminance uniformity and Mura test	8 Uniformity Measurements, IDMS v1.03b	<10% non-uniformity on 80% video level	21% non-uniformity on 80% video level

Test	Test Method	Results	
		MDPC-8127	Predicate device
Stability of luminance and chromaticity response	Luminance and chromaticity characteristics of the display measured with temperature and time	Deviation from target luminance (450 cd/m <sup>2</sup> ): ±0.44% Variations for luminance and chromaticity: < 5% deviation	Deviation from target luminance (350 cd/m <sup>2</sup> ): ±0.2% Variations for luminance and chromaticity: < 2% deviation
Bidirectional reflection distribution function	11. Reflection Measurements, IDMS v1.03b	Specular reflection coefficient: 1.90% Diffuse reflection coefficient: 2.87%	Specular reflection coefficient: 1.69% Diffuse reflection coefficient: 2.21%
Gray tracking	6.15 Gray-scale Color Changes, IDMS v1.03b	+/- 0.01 Δu'v' White point at D65: +/- 0.01 Δu'v'	+/- 0.002 Δu'v' White point at D65: +/- 0.002 Δu'v'
Color scale	6. Gray- and Color-Scale Measurement, IDMS v1.03b	Average color error < 1 ΔE <sub>00</sub> Maximum color error < 3 ΔE <sub>00</sub>	Average color error < 2 ΔE <sub>00</sub> Maximum color error < 5 ΔE <sub>00</sub>
Color gamut volume	5.18.1 Relative Gamut Area, IDMS v1.03b	2D color gamut wrt sRGB: 137.1% 2D color gamut overlapped with sRGB: 99.6%	2D color gamut wrt sRGB: 99.4% 2D color gamut overlapped with sRGB: 98.4%

### 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.