510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K172922

B. Purpose for Submission:

New display

C. Manufacturer and Instrument Name:

Barco N.V.
MMPC-4127F1 (PP27QHD)

D. Type of Test or Tests Performed:

Digital pathology display

E. System Descriptions:

1. Device Description:

The MMPC-4127F1 (PP27QHD) is a 27" color LCD flat panel medical display with a fine pixel pitch that can be calibrated to the sRGB gamut. The display is designed to view scanned digital images of formalin-fixed, paraffin-embedded (FFPE) tissue slides, using IVD-labeled whole slide imaging systems. Display accessories include QAWeb quality assurance software, DisplayPort cable, USB cable and AC power cord cables. The display has the following specifications :

Display Characteristics and Electro-Optical Performance	
Display technology	IPS LCD
Native Resolution	2560 x1440
Display LUT	≥ 10 bit / sub-pixel
Pixel Pitch (Horizontal) (mm)	0.2331
Pixel pitch (Verical) (mm)	0.2331
Active screen (Diagonal) (mm / inch)	685.8 / 27.0
Active screen (Width) (mm)	596.74
Active screen (Height) (mm)	335.66
Contrast Ratio - (typical)	1000:1
Luminance stabilization	+2% / -2% front sensor
Maximum Luminance (typical) (cd/m²)	500
DICOM Calibrated Luminance (Typical) (cd/m²)	350

Luminance non-uniformity (per DIN6868- 157), diagnostic room class	<25% on 9 points, 10%/80% luminance
Response Time (typical) (ms)	12
Response Time (max) (ms)	24
Calibration Performance	
Supported color spaces	sRGB, DICOM, native
Average dE2000 deviation from sRGB	<2 on 6x6x6 grid
Maximum dE2000 deviation from sRGB	<5 on 6x6x6 grid
White point chromaticity stabilization	+/-0.01 u'v'
Gray tracking (per IEC 62563)	+/-0.01 u'v'
Grayscale transfer function deviation	<10% on 18 points
Calibration Software	MediCal QAWeb
Environmental Specifications	
Operational Temperature (min/max) (°C)	10 / 40
Within specification temperature (min/max) (°C)	10 / 35
Power Consumption (@ 100-240VAC typical) (W)	120

2. Principles of Operation:

   The MMPC-4127F1 (PP27QHD) display is to be used to view scanned digital images of formalin-fixed, paraffin-embedded (FFPE) tissue slides, using IVD-labeled whole slide imaging (WSI) systems, which are automated digital slide creation, management, viewing and analysis systems designed for scanning and digitizing surgical pathology slides prepared from FFPE tissues. The digitized images can then be displayed and reviewed on the MMPC-4127F1 (PP27QHD) monitor for interpretation by pathologists for clinical purposes.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _____ or No ___X_____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ____X____

4. Specimen Identification:

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

5. Specimen Sampling and Handling:

Specimen sampling, which includes FFPE tissues, is performed by clinicians. Biopsy specimens are processed by trained healthcare professionals.

6. Calibration:

   The MMPC-4127F1 (PP27QHD) display is calibrated using a built-in front sensor. Calibrations are initiated by the QAWeb quality assurance software and performed as a background activity.

7. 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.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes___X_____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.3700

2. Classification:

   Class II (special controls)

3 Product code:

   PZZ, Digital Pathology Display

4. Panel:

   88 - Pathology

G. Intended Use:

1. Indication(s) for Use:

   The Barco MMPC-4127F1 (PP27QHD) device is intended for in vitro diagnostic use to display digital images of histopathology slides acquired from IVD-labeled whole-slide

imaging scanners that have been validated for use with this device, for review and interpretation by pathologists. The display is not intended for use with digital images from frozen section, cytology, or non-formalin-fixed, paraffin embedded (non-FFPE) hematopathology specimens.

2. Special Conditions for Use Statement(s):

   For in vitro diagnostic (IVD) use only

   For prescription use only

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   Philips IntelliSite Pathology Solution (PIPS) - PP27QHD display

   K172174

2. Comparison with Predicate Device:

Similarities		
Item	Device Barco MMPC-4127F1 (PP27QHD)	Predicate PIPS - PP27QHD
Dithering function	Temporal and spatial dithering is implemented in the medical display	Same
Supported color spaces	Supported color spaces including sRGB: - DICOM - Native	Same
Interface	Supported display interface including USB 2.0: DVI-D dual-link	Same

Differences		
Item	Device Barco MMPC-4127F1 (PP27QHD)	Predicate PIPS - PP27QHD
Intended Use	The Barco MMPC-4127F1	The Philips IntelliSite

Differences		
Item	Device Barco MMPC-4127F1 (PP27QHD)	Predicate PIPS - PP27QHD
	(PP27QHD) display device is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret to display (or view) digital images of surgical pathology slides acquired from FDA-cleared IVD-labeled whole-slide imaging scanners that have been validated with this device, for review and interpretation by pathologists. as described in the user guide. The display is not intended for use with frozen section, cytology, or non-formalin-fixed, paraffin embedded (FFPE) hematopathology specimens.	Pathology Solution (PIPS) is an automated digital slide creation, viewing, and management system. The PIPS is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. The PIPS is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. The PIPS comprises the Image Management System (IMS), the Ultra Fast Scanner (UFS) and Display. The PIPS is for creation and viewing of digital images of scanned glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using PIPS.
Configuration	Display only	PIPS system includes Ultra Fast Scanner (UFS), Image Management System (IMS) and Display (PP27QHD)

I. Special Control/Guidance Document Referenced:

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.

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)

AAMI ANSI IEC 62366-1:2015: Medical devices - Application of usability engineering to medical devices

ISO 14971 Second edition 2007-03-01(5-40) Medical devices - application of risk management to medical devices.

J. Performance Characteristics*:*

1. Analytical Performance:

   a. *Accuracy*:

      Not applicable

   b. *Precision/Reproducibility*:

      Not applicable

   c. *Linearity*:

      Not applicable

   d. *Carryover*:

      Not applicable

   e. *Interfering Substances*:

      Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

   Display Equivalency Study:

   Technical performance testing for Barco MMPC-4127F1 (PP27QHD) display was performed. The new display was compared to the display that is part of the predicate device PIPS - PP27QHD (2.5). Testing included assessment of the following parameters:

luminance, color, noise, resolution, pixel defects, artifacts, temporal response, grayscale, and specular and diffuse coefficients. All testing results demonstrated that the Barco MMPC-4127F1 (PP27QHD) display is equivalent to the predicate device display.

Luminance: The Barco MMPC-4127F1 (PP27QHD) and the predicate device use the same LCD panel. The luminance remains within the specified range of 350 cd/m^2 $\pm$ 10 %, and the luminance stability is within approximately 0.4%.

Color: The color scale response when sRGB calibrated and the sRGB gamut are similar between the PP27QHD and the predicate device. The color stability over time is within the specified maximum deviation of 0.0050 in both x and y.

Noise: The PP27QHD and the predicate device use the same LCD panel and therefore the noise and the noise power spectrum are identical. The RMS (image variance) for multiple video levels of both luminance and color as measured on gray fields were the same.

Resolution: The MTF of the display system was measured according to the method described by Hans Roehrig et al. (2004) [Hans Roehrig, Jerry Gaskill, Jiahua Fan, Ananth Poolla, Chadwick Martin, "In-field evaluation of the modulation transfer function of electronic display devices", Proc. SPIE 5367, Medical Imaging 2004: Visualization, Image-Guided Procedures, and Display, (5 May 2004)]. The MTF of the camera system was approximately 98% at the display's Nyquist frequency. The spatial resolution of the panel is 109 dpi (dots per inch).

Artifacts: The PP27QHD and the predicate are flat panel displays. There is no problem of impedance matching in a purely digital system, ringing and ghosting are not present. This is identical for the PP27QHD and the predicate device.

Temporal response: The PP27QHD and the predicate device use the same LCD panel and therefore the temporal response is identical. The response time is approximately 12 ms and the maximum response time is 24 ms.

Grayscale: There is no difference in greyscale behavior between the PP27QHD and the predicate device when calibrated to sRGB (default setting).

Specular and diffuse coefficients: The same LCD panel is used in both the predicate and the PP27QHD and therefore the specular and diffuse coefficients in functions of wavelength are identical.

K. 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.

L. Conclusion:

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