510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K243871

B Applicant

Philips Medical Systems Nederland B.V.

C Proprietary and Established Names

Philips IntelliSite Pathology Solution (PIPS) 5.1

D Regulatory Information

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

II Review Summary:

A Purpose for Submission:

Addition of a new display (monitor) MDCC-4430 from manufacturer Barco.

B Type of Test:

The Philips IntelliSite Pathology Solution (PIPS) 5.1 is an automated digital slide creation, viewing, and management system.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Philips IntelliSite Pathology Solution (PIPS) 5.1 is an automated digital slide creation, viewing, and management system. The PIPS 5.1 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 5.1 is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens.

The PIPS 5.1 comprises the Image Management System (IMS) 4.2, Ultra-Fast Scanner (UFS), Pathology Scanner SG20, Pathology Scanner SG60, Pathology Scanner SG300 and Philips PP27QHD display, a Beacon C411W display or a Barco MDCC-4430 display. The PIPS 5.1 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 5.1.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The PIPS 5.1 device is an automated digital slide creation, viewing and management system. PIPS 5.1 consists of the following components:

a. Whole slide imaging scanners:
   i. Ultra Fast Scanner (UFS)
   ii. Pathology Scanner Second Generation (SG) with different versions for varying slide capacity: Pathology Scanner SG20, Pathology Scanner SG60, Pathology Scanner SG300
b. Image Management System (IMS) 4.2
c. Philips PP27QHD, Beacon C411W or Barco MDCC-4430 display

There are no changes to the whole slide imaging scanners, IMS 4.2 and PP27QHD display since the previous clearance in K233204. There are no changes to the Beacon C411W display since the previous clearance in K242848. The MDCC-4430 display is a 4MP display.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Philips Intellisite Pathology Solution (PIPS)

B Predicate 510(k) Number(s):

K242848

C Comparison with Predicate(s):

Device & Predicate Device(s):	K242848	K243871
Device Trade Name	Philips IntelliSite Pathology Solution 5.1	Philips IntelliSite Pathology Solution 5.1
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Philips IntelliSite Pathology Solution (PIPS) 5.1 is an automated digital slide creation, viewing, and management system. The PIPS 5.1 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 5.1 is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. The PIPS 5.1 comprises the Image Management System (IMS) 4.2, Ultra-Fast Scanner (UFS), Pathology Scanner SG20, Pathology Scanner SG60, Pathology Scanner SG300 and Philips PP27QHD display or a Beacon C411W display. The PIPS 5.1 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	The Philips IntelliSite Pathology Solution (PIPS) 5.1 is an automated digital slide creation, viewing, and management system. The PIPS 5.1 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 5.1 is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. The PIPS 5.1 comprises the Image Management System (IMS) 4.2, Ultra Fast Scanner (UFS), Pathology Scanner SG20, Pathology Scanner SG60, Pathology Scanner SG300 and PP27QHD display or a Beacon C411W display or a Barco MDCC-4430 display. The PIPS 5.1 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

	pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using PIPS 5.1.	safeguards to assure the validity of the interpretation of images obtained using PIPS 5.1.
General Device Characteristic Differences		
Display (Monitor)	Barco PP27QHD Shenzhen Beacon C411W	Barco PP27QHD Shenzhen Beacon C411W Barco MDCC-4430
Physical display size	Barco PP27QHD 648.5 mm x 423 mm x 91.3 mm (with backlight disc)	Barco MDCC-4430 714 mm x 478 mm x 74 mm
Calibration software	MediCal QAWeb Agent software version 1.13.12 installed on the workstation	QAWeb Enterprise version 2.14.0 installed on the workstation
Display Pixel Pitch	0.2331 mm x 0.2331mm	0.256 mm x 0.256 mm

VI Standards/Guidance Documents Referenced:

- IEC 60601-1 Edition 3.2 (2020) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6 (4th Ed) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 62471:2006 Photobiological safety of lamps and lamp systems
- ISO 14971:2019 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:

Display Equivalency Study:

Technical performance testing for the Barco MDCC-4430 display was performed and compared with the Barco PP27QHD display. The test results are summarized in the Table below.

Summary of Results

Display Characteristics	Test Method	Results	
		Subject Device Barco MDCC-4430	Predicate Device Barco PP27QHD
1. Spatial resolution	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) https://doi.org/10.1117/12.536250	Both horizontal and vertical MTFs are greater than 70% at Nyquist frequency	Both horizontal and vertical MTFs are greater than 75% at Nyquist frequency
2. Pixel defects	Visual assessment – Stuck ON and Stuck OFF per Defective Pixels (Section 7.6 in IDMS version 1.1)	"On Pixels": 0 "Partial On Pixels": ≤ 7 "Off Pixels" + "Dim Pixels": ≤ 9 "Partial On Pixels" within a circle of 10 mm diameter <= 2 "Off Pixels" within a circle of 10 mm diameter <= 2	"On Pixels": 0 "Partial on Pixels": ≤ 6 "Off Pixels": ≤ 5 "Partial on Pixels" + "Off Pixels" within a circle of 10 mm diameter <= 3
3. Artifacts	Visual assessment (section 4.6 in IDMS version 1.1) Image retention	Image retention after 1 hour < 0.65%	Image retention after 1 hour < 0.65%
4. Temporal response	Gray-to-Gray Response time (section 10.2.3 in	Gray-to-gray response time = 8.1ms (minimum), 23.3	Gray-to-gray response time = 5.2ms (minimum), 9.7ms

Display Characteristics	Test Method	Results	
		Subject Device Barco MDCC-4430	Predicate Device Barco PP27QHD
	IDMS version 1.1) 9x9 points, equal lightness	ms (average) and 39.0 ms (maximum)	(average) and 17.4ms (maximum)
5. Maximum and minimum luminance (achievable and recommended)	Vantage-Point Suite of Measurement (section 2.4 in IDMS version 1.1) Sequential Contrast (IDMS version 1.1, section 5.10)	The maximum and minimum achievable luminance values are 1500 and 0.25 cd/m² respectively. The calibrated luminance is 350 cd/m². The contrast ratio is Typical: 2000:1 Observed: 1741:1	The maximum and minimum achievable luminance values are 550 and 0.3 cd/m² respectively. The calibrated luminance is 350 cd/m². The contrast ratio is Typical: 1000:1. Observed: 1360:1
6. Grayscale	Grayscale (IDMS version 1.1, section 6.1)	Maximum luminance error from sRGB transfer function (ΔL): 2.02 cd/m² at DLL=213 Maximum luminance error over reference luminance (ΔL/L): 1.32% at DLL=152	Maximum luminance error from sRGB transfer function (ΔL): 2.05 cd/m² at DLL=201 Maximum luminance error over reference luminance (ΔL/L): 7.02% at DLL=6
7. Luminance uniformity	Sampled uniformity (IDMS version 1.1, section 8.1) and area uniformity (IDMS version 1.1, section 8.2)	Non-uniformity is 2.69% at 80% video level.	Non-uniformity is 11.6% at 80% video level.
8. Stability of luminance and chromaticity response with temperature and lifetime	Full-screen white (section 5.3 IDMS version 1.1)	Maximum luminance deviation from target (350 cd/m²) over temperature: 0.36% Maximum luminance deviation from target (350 Cd/m²) over time: 0.46% in 20 hours Maximum chromaticity deviation from target (D65) over time: (Δx=0.0007, Δy=0.0017) in 20 hours	Maximum luminance deviation from target (350 Cd/m²) over temperature: 0.59% Maximum luminance deviation from target (350 Cd/m²) over time: 0.69% in 20 hours Maximum chromaticity deviation from target (D65) over time: (Δx=0.0021, Δy=0.0043) in 20 hours
9. Bidirectional reflection coefficients	Small source reflection (section 11.6 IDMS version 1.1) for specular component.	Specular reflection coefficient: 1.85% Diffuse reflection coefficient: 2.47%	Specular reflection coefficient:1.69% Diffuse reflection coefficient: 2.21%

Display Characteristics	Test Method	Results	
		Subject Device Barco MDCC-4430	Predicate Device Barco PP27QHD
	Hemispherical reflection specular excluded (section 11.3 in IDMS version 1.1) with Diagnostic: characterizing hemisphere uniformity (section 11.12) for diffuse component.		
10. Gray tracking	AAPM Task Group 196 Report, and IDMS version 1.1 section 6.15	Max Δu'v' from measured white chromaticity at target D65 (as of L > 5 cd/m²): ± 0.0006	Max Δu'v' from measured white chromaticity at target D65 (as of L > 5 cd/m²): ± 0.0010
11. Color Scale	Primary color scales (section 6.2 IDMS version 1.1) and Color-Signal White (Section 5.4.1 IDMS version 1.1)	Average color error <2 ΔE_{00} Maximum color error <5 ΔE_{00} Color signal white ratio = 1.00	Average color error <2 ΔE_{00} Maximum color error <5 ΔE_{00} Color signal white ratio = 1.00
12. Color gamut volume	Chromaticity gamut area (IDMS version 1.1, section 5.18 and subsection 5.18.1)	Color gamut area wrt sRGB: 99.13% sRGB overlap: 98.32%	Color gamut area wrt sRGB: 98.57% sRGB overlap: 97.70%

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.