



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K241871

B Applicant

Philips Medical Systems Nederland B.V.

C Proprietary and Established Names

Philips IntelliSite Pathology Solution

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) C411W from manufacturer Shenzhen Beacon.

B Type of Test:

The Philips IntelliSite Pathology Solution (PIPS) 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) 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 Philips PP27QHD display or a Beacon C411W 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The Philips IntelliSite Pathology Solution (PIPS) is an automated digital slide creation, viewing and management system. 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. The PIPS does not include any automated image analysis applications that would constitute computer aided detection or diagnosis. The pathologists only view the scanned images and utilize the image review manipulation software in the PIPS.

PIPS consists of two subsystems and a display component:

- Ultra Fast Scanner (UFS)
- Image Management System (IMS)
- Clinical Display

The UFS subsystem scans coverslipped glass slides to produce whole slide images (WSI) of the tissue material mounted on the pathology glass slides. The slides are placed in racks which are then placed in rack slots in the UFS. The scanning procedure requires minimal user interaction. The UFS consists of optical, mechanical, and electronic elements as well as software components.

The IMS is a software only subsystem and consists of the IMS Application Server and Storage software and IMS Viewer software installed on compatible server hardware. Functionality of the IMS includes the ability to view WSIs, organize workload, and annotate and bookmark scanned slide images. The pathologist uses the IMS Viewer to interact with the IMS Server to store and retrieve the pathology data (digitized slide images, patient data).

The new display Beacon C411W is connected to a client computer with access to the IMS Viewer. The display is calibrated using the built-in calibration sensor and software tool, which automatically perform a periodic calibration. The pathologist uses the display for viewing Whole Slide images using the IMS Viewer software.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Philips Intellisite Pathology Solution

B Predicate 510(k) Number(s):

K192259

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K241871</u>	<u>K192259</u>
Device Trade Name	Philips Intellisite Pathology Solution	Same
General Device Characteristic Similarities		
Intended Use /Indications For Use	<p>The Philips IntelliSite 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.</p> <p>The PIPS comprises the Image Management System (IMS), the Ultra Fast Scanner (UFS) and Philips PP27QHD display or a Beacon C411W display. The PIPS is for creation and viewing of digital images of scanned glass slides that would otherwise be appropriate for</p>	<p>The Philips IntelliSite 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.</p> <p>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</p>

	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.	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.
Display Pixel Pitch	0.2331 mm x 0.2331mm	Same
Display Calibration hardware	Built-in front sensor	Same
General Device Characteristic Differences		
Display	Shenzhen Beacon C411W	Barco PP27QHD
Technology	Thin Film Transistor	IPS technology with a-Si Thin Film Transistor
Physical display size	646 mm x 423 mm x 91.3 mm	648.5 mm x 423 mm x 91.3 mm (with backlight disc)
Calibration software	Beacon QA Manager software version 1.1 installed on the workstation	MediCal QAWeb Agent software version 1.13.12 installed on the workstation

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.
2. IEC 60601-1 Edition 3.2 (2020) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
3. IEC 60601-1-6 (4th Ed) Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard Usability.
4. IEC 62471:2006 Photobiological safety of lamps and lamp systems.
5. 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 Beacon C411W display was performed and compared with the Barco PP27QHD display. The test results are summarized in the Table 1 below.

In addition, the existing functional, safety, user and system integration requirements related to the display were verified and validated.

Table 1: Display Equivalency Test

Test	Test Method	Results	
		Subject Device Beacon C411W	Predicate Device Barco PP27QHD
1. Spatial resolution	Measurement of the Modulation Transfer Function (MTF) IDMS v 1.03, section 7.7	Both horizontal and vertical MTFs are greater than 86% at Nyquist frequency	Both horizontal and vertical MTFs are greater than 75% at Nyquist frequency
2. Pixel defects	Measurements (counts) of pixel defects IDMS v 1.03, section 7.6 Defective Pixels	Total number of pixel defects ≤ 5 Total number of bright and dark pixels within a circle of 10 mm ≤ 1	Total amount of pixel defects ≤ 6 Total number of bright and dark pixels within a circle of 10 mm ≤ 3
3. Artifacts	Measurement of image retention after 1 hour IDMS v 1.03, section 10.4 Artifacts and Irregularities	0.43%	< 0.65%
4. Temporal response	Measurement of response time IDMS v 1.03, 10.2(section 10.2.2 Response Time)	The response time is 16.39 ms	The response time is 15 ms

Test	Test Method	Results	
		Subject Device Beacon C411W	Predicate Device Barco PP27QHD
5. Maximum luminance and contrast ratio	Maximum and minimum luminance (achievable and recommended) and contrast ratio IDMS v 1.03, section 2.4 Vantage-Point Suite of Measurements	Minimum achievable: 0.375 cd/m ² Maximum achievable: 357 cd/m ² Calibrated to max. recommended: 350 cd/m ² The contrast ratio is 933.33:1	Minimum achievable: ≤ 0.3 cd/m ² Maximum achievable: 550 cd/m ² Calibrated to max. recommended: 350 cd/m ² The contrast ratio is 1000:1
6. Grayscale	Measurement of the mapping between image values and the luminance IDMS v1.03, section 6.1 Gray Scale	Maximum luminance error from sRGB transfer function (ΔL) = 0.72 cd/m ² at DLL=120; Maximum luminance error over reference luminance ($\Delta L/L$) = 2.9% at DLL=15	Maximum error from sRGB transfer function $\leq 0.99\%$
7. Luminance uniformity	Luminance uniformity testing IDMS v 1.03, section 8.1.1 Sampled Contrast Uniformity	Non-uniformity is 20% at 80% video level.	Non-uniformity is < 21% at 80% video level 80%
8. Stability of luminance and chromaticity response with temperature and lifetime	Luminance and chromaticity characteristics of the display measured with temperature and time based on IDMS v 1.03, section 10 Temporal Measurements	Luminance deviation from target (350 cd/m ²) with temperature: 7.8%; Luminance deviation from target (350 cd/m ²) over time: 1.24%; Chromaticity deviation from target (D65): (0.317,0.334)	Deviation from target luminance (350 cd/m ²) with temperature: < 10% Variations for luminance and chromaticity over time: < 2% deviation
9. Bidirectional reflection coefficients	Measurement of specular and diffuse reflection coefficient IDMS v 1.03, section 11.12 Reflection Measurements	Specular reflection coefficient, averaged between 400 nm and 740 nm: 1.83% Diffuse reflection coefficient, averaged between 400 nm and 740 nm: 2.33%	Specular reflection coefficient: 1.69% Diffuse reflection coefficient: 2.21%
10. Gray tracking	Measurement of gray tracking (stability of neutral grey colors)		

Test	Test Method	Results	
		Subject Device Beacon C411W	Predicate Device Barco PP27QHD
	IDMS v 1.03, section 6.15 Gray-scale Color Changes	White point deviation from D65 = $0.0013 \Delta u'v'$	White point at D65: $\leq 0.002 \Delta u'v'$
11. Color Scale	Determine the color error IDMS v1.03, section 6.2 Primary Color-Scale	Average color error = $0.95 \Delta E_{00}$ Maximum color error = $1.47 \Delta E_{00}$ Color signal white ratio = 1.00	Average color error $< 2 \Delta E_{00}$ Maximum color error $< 5 \Delta E_{00}$ Color signal white ratio = 1.00
12. Color gamut volume	Measurement of the color gamut volume IDMS v1.03, section 5.18.1 Relative Gamut Area	2D color gamut area with respect to sRGB: 110.4% 2D color gamut area overlapped with sRGB: 98.5%	2D color gamut area with respect to sRGB: 98.6% 2D color gamut area overlapped with sRGB: 97.7%

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.