510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K172174

B. Purpose for Submission:

New display PP27QHD

C. Manufacturer and Instrument Name:

Philips Medical Systems Nederland B.V.
Philips IntelliSite Pathology Solution (PIPS)

D. Type of Test or Tests Performed:

Digital pathology whole slide imaging system

E. System Descriptions:

1. Device Description:

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

The PIPS consists of two subsystems and a display:

- Ultra Fast Scanner (UFS) (for software UFS 1.7.1.1, for hardware 4522 010 50003)
- Image Management System (IMS) (for software IMS 2.6.1)
- Display (PP27QHD)

The UFS consists of optical, mechanical, electronic and software elements to scan FFPE tissue mounted on glass slides at a resolution of 0.25 µm per pixel, which is equivalent to a 40x objective, to create digital Whole Slide Images (WSI). The UFS has a capacity of 300 slides (15 glass slide racks with up to 20 slides per rack). After the slide racks are loaded into the UFS, the UFS automatically detects and starts scanning the slides. CCD cameras are used to capture color images from the back-lit tissue specimen. An LED light source employs top-lit illumination to capture the barcode and back-lit illumination for tissue scanning. The stage (STG) and Image Capturing Unit (ICU) are fixed to each other and to the base frame to ensure correct positioning of the slide and to suppress external disturbances. Proprietary software is used for image processing during acquisition.

Philips' proprietary format, iSyntax, is used to store and transmit the images between the UFS and the IMS.

The IMS is a software only subsystem to be used with the Display. Functionality of the IMS includes the ability to view images, organize workload, and annotate and bookmark scanned images. The user manual for PIPs specifies compatible computer environment hardware and software that is not included as part of the system.

The display is a custom developed 27" color LCD flat panel medical display. The dithering functionality is implemented on the display itself (PP26QHD). The dithering operations in the display system do not affect the image characteristics, as both the display PS27QHDCR and the display PP27QHD (MMPC-4127F1) use the same temporal dithering schematic and the same 256 pseudo random sequence. The display has the following specifications:

- 3.6 Megapixel
- Resolution 2560 x 1440
- Backlight : White LED
- Frame rate: 60 Hz ; Refresh rate: 60 Hz
- Connectivity : 100 Mbit/sec or 1 Gbit Ethernet connection to internet/intranet

The different subsystems of the PIPS are connected over an IT network at the user site. The IT hardware/software that supports the IMS Application Server & Storage software is not provided as part of the PIPS, but may be located in a central server room separate from the workstation with the IMS viewing software and Display. The communication of data between UFS and IMS is via a customer provided wired network or a direct connected cable between these subsystems. PIPS includes a display that has been validated as part of the pivotal clinical study.

The PIPS allows pathologists to view and evaluate digital images of formalin-fixed, paraffin-embedded (FFPE) tissue slides that would otherwise be appropriate for manual visualization by conventional brightfield (light) microscopy. The PIPS does not include any automated Image Analysis Applications that would constitute computer aided detection or diagnosis.

2. Principles of Operation:

The PIPS device is an automated system designed for scanning and digitizing surgical pathology slides prepared from FFPE tissue. These digitized images can then be reviewed and interpreted by pathologists for clinical (patient care) purposes.

Prior to scanning the slide on the UFS, the technician conducts quality control of the slides per the laboratory's standards. The technician then places the slides into racks, which are loaded into the UFS. The handler in the UFS automatically moves a slide from the storage area to the scanning area. A macro image is generated that includes the slide label and a low power image of the entire slide. The system then determines regions of

interest in the tissue to scan, which are subsequently scanned at high resolution (0.25 µm per pixel). After the slide is scanned, it is returned to the same slot of the same rack from which it was originally obtained.

The images scanned in the UFS are compressed using Philips' proprietary iSyntax format and are transmitted to the IMS subsystem. The images can be reviewed through the IMS only. The IMS allows the user to identify, organize and execute the worklist. The pathologist selects the first slide, navigates around the slide and views the images at the desired magnification. The pathologist is responsible for ensuring the validity of the interpretation of the digital images obtained from the PIPS.

3. Modes of Operation:

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

   Yes ___X_____ or No _____

   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 UFS performs a series of automatic calibrations. Each whole slide image (WSI) displays a flag that indicates if the scanner was in a calibrated or un-calibrated state, thereby providing a visual indicator to the viewer of the WSI. Users also may manually initiate a calibration, if desired. By default, calibrations are triggered every 4 hours (or 200 slides). Depending on circumstances, this frequency can result in a calibration in the middle of a run. To prevent such an event, the user may manually initiate the calibration process prior to scanning a batch (e.g., during slide processing).

   Manual calibration may also be initiated if the UFS detects that the instrument is not calibrated during a slide scan. The system will display a message to the operator requesting whether the user wishes to accept the slide as is or re-calibrate and rescan the

slide. As a precautionary measure, the system displays a warning message on images that were scanned using an un-calibrated scanner. In addition to the automated calibration within the UFS, routine field service visits are planned to calibrate the UFS.

The display is calibrated using a built-in front sensor. Calibrations are initiated by the QAWeb agent and performed as a background activity. The IMS subsystem does not require calibration.

7. Quality Control:

   It is the responsibility of the laboratory staff to conduct and maintain quality control of the slides per their laboratory standards (e.g., staining, cover-slipping, barcode placement) prior to loading the slides into the UFS. After completing a scan, the operator is instructed by the instructions for use to check image data and image quality using the IMS Viewer. In addition to calibrations, quality checks for the display are initiated by the QAWeb agent 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:

   PSY

4. Panel:

   88 - Pathology

G. Intended Use:

1. 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 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.

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)

   DEN160056

2. Comparison with Predicate Device:

Similarities		
Item	Device PIPS (2.6.1)	Predicate PIPS (2.5)
Intended use /Indication 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	Same

Similarities		
Item	Device PIPS (2.6.1)	Predicate PIPS (2.5)
	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.	
Ultra Fast Scanner (UFS) (for software UFS1.7.1.1	The UFS consists of optical, mechanical, electronic and software elements to scan FFPE tissue mounted on glass slides at a resolution of 0.25 µm per pixel, which is equivalent to a 40x objective, to create digital Whole Slide Images (WSI). The UFS has a capacity of 300 slides (15 glass slide racks with up to 20 slides per rack). After the slide racks are loaded into the UFS, the UFS automatically detects and starts scanning the slides. CCD cameras are used to capture color images from the back-lit tissue specimen.	Same

Differences		
Item	Device PIPS (2.6.1)	Predicate PIPS (2.5)
Display	Temporal and spatial dithering is implemented in the medical display Supported color spaces including sRGB:	Temporal and spatial dithering is implemented on the graphics board sRGB is supported

Differences		
Item	Device PIPS (2.6.1)	Predicate PIPS (2.5)
	- DICOM - Native Calibration and quality checks performed using a built-in sensor and QAWeb Agent software Supported display interface including USB 2.0: - DVI-D dual-link	 Calibration and quality checks performed using LCD sensor and Nucleus software Display Port (DP) Universal Serial Bus (USB 2.0)

I. Special Control/Guidance Document Referenced (if applicable):

The special controls as described in 21 CFR 864.3700(b).

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/ISO 15223-1: Symbols for use in the labeling of medical devices

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

ASTM D4169-14: Standard Practice for Performance Testing of Shipping Containers and Systems

IEC 62304:2006 (edition 1.0): Medical device software - Software life- cycle processes

IEC 61010-1:2010: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

IEC 61010-2- 101:2015: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

IEC 60601-1-2 (4th Ed): Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests

IEC 62471: 2006: Photobiological Safety Of Lamps And Lamp Systems

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 the PP27QHD display was performed. The new display was compared to the display that is part of the predicate device PIPS (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 PP27QHD display is equivalent to the predicate device display.

Luminance: The 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.