510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K203845

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 Submission/Device Overview:

A Purpose for Submission:

Philips Medical Systems Nederland B.V., submitted K203845 due to a significant change to the Image Management System (IMS) subsystem of their Philips IntelliSite Pathology Solution (PIPS, K192259). The change is as follows: client-side rendering.

B Type of Test:

Not applicable.

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 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:

Philips IntelliSite Pathology Solution (PIPS) is an automated digital slide creation, viewing, and management system. PIPS consists of two subsystems and a display component:

Ultra-Fast Scanner (UFS): There are no major changes to the UFS cleared under K172174. In summary, the UFS subsystem scans cover-slipped glass slides at 40x magnification to produce high-quality Whole Slide Images (WSIs) of the tissue material mounted on the 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 has a loading capacity for large batches (up to 300 slides). On the touchscreen the scanning progress is shown. 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 UFS consists of optical, mechanical and electronic elements as well as software components. The UFS is located and operated on site in healthcare institutions such as clinical pathology laboratories, etc.

Image Management System (IMS): 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 WSIs. The IMS Viewer will operate in the user's work environment using the display (component of the PIPS) to display WSIs. The IMS Application Server and Storage software will operate in a controlled environment, typically a server room separate from the pathology departments. One or more client computers with intranet/internet connection to the IMS, meeting the minimum requirements (see Table 16-3 and Table 16-4 of Section 16.3.1), and display are required for viewing images from the IMS. Client computers are

not part of the PIPS and will either be located in healthcare institutions such as clinical pathology laboratories, etc. or in a pathology office.

Client-Side Rendering: Image processing is performed at the client computer (i.e., client-side rendering) instead of at the server side. Client-side rendering utilizes Web Graphics Library (WebGL), which is a JavaScript Application Programming Interface (API), for image processing within a browser. WebGL allows using the computational power of a Graphics Processing Unit (GPU) on the client computer. Offloading image processing to the GPU speeds up rendering. A Philips service engineer can only configure the server or client-side rendering option. This option is called "Use my computer for image processing". When the option "Use my computer for image processing" is enabled, additional requirements with respect to the Video Card are applicable as follows: Video card minimum specifications - GPU Memory: 4GB; GeForce GTX 1050 Ti or similar; Memory bandwidth: 112 GB/s. The recommended browser for client-side rendering is Chrome.

Philips PP27QHD Display: There are no changes introduced for the display. In summary, the Philips PP27QHD display 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 perform automatically a periodic calibration. The pathologist uses the display for viewing WSIs using the IMS Viewer software.

B Instrument Description Information:

1. Instrument Name:

   Philips IntelliSite Pathology Solution (PIPS)

2. Specimen Identification:

   Not applicable.

3. Specimen Sampling and Handling:

   Not applicable.

4. Calibration:

   Not applicable.

5. Quality Control:

   Not applicable.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Philips IntelliSite Pathology Solution (PIPS)

B Predicate 510(k) Number(s):

K192259

C Comparison with Predicate:

Device & Predicate Device(s):	K203845	K192259
Device Trade Name	Philips Intellisite Pathology Solution (PIPS)	Philips Intellisite Pathology Solution (PIPS)
General Device Characteristic Similarities		
Intended Use/Indications 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	Same

	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.	
General Device Characteristic Differences		
Image Review and Manipulation Software – Computer Environment	To reduce the network bandwidth requirements and improve scalability, an option is added (configurable by a Philips service engineer) that moves the image processing logic (i.e. decompression, sharpening and contrast enhancement) from the server side to the client side. The programming language is JavaScript.	Most image processing logic (e.g. decompression, sharpening and contrast enhancement) are performed on the server side. The programming language is C#.

VI Standards/Guidance Documents Referenced:

- ISO 14971: 2007: Medical devices – Application of risk management to medical devices
- ISO 15223-1: 2016: Medical devices: Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
- IEC 62304:2006 Amd 1: 2015: Medical device software – Software life-cycle processes
- IEC 62366-1: 2015: Medical devices – Application of usability engineering 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:

The K203845 was submitted to seek clearance for one significant change, the client-side rendering to the Image Management System (IMS), the software subsystem of the Philips IntelliSite Pathology Solution (PIPS, K192259).

Verification testing activities have been performed to support the substantial equivalence determination for the modified IMS containing the client-side rendering change which included:

1. A pixel comparison test to determine pixel equivalence using the 'Regression SingleTest' methodology that loads a reference image and reads the displayed pixel from the user interface into a test image to verify that the displayed RGB output values of each pixel are identical with the reference image input.
   Reference Data Set: A Reference Data Set is created by importing a set of 85 Whole Slide Images (WSIs) in a clinically validated product and storing from the pixels from 3377 selected regions of these WSIs in png images (i.e. reference png image) with $1.2*10^9$ pixels.
   Test acceptance criteria: The displayed RGB output values of each pixel in the test image of the proposed product need to be identical with the reference bitmap image from the clinically validated product. When all test images are identical with the related reference bitmap images then the test results meet the acceptance criteria and the conclusion is that the test 'passed'.
   Test execution: During the test execution, the same WSIs used to create the Reference Data Set are imported in the proposed product. For this RegressionSingleTest a version of the IMS HTML viewer is used that does not contain users controls but allows for retrieval of the pixel data by a test framework.

IMS HTML viewer test method: The RegressionSingleTest executes the following steps for each browser (i.e., Chrome):

1. Import 85 WSIs from the Reference Data Set in the proposed IMS.
2. For each of the 3377 selected regions:
   - Open the region in the IMS HTML viewer,
   - Read the displayed pixels from the User Interface (HTMLCanvasElement class) into a test image,
   - Load the pixels from the reference bitmap image,
   - Compare the displayed pixels (RGB) of the test image with the pixels in the related reference bitmap image for equivalence.
3. When all 3377 test images are identical with the reference bitmap images then report 'passed', otherwise report 'fail'.

Test Results: All test results passed.

2. Testing of requirements, risk control measures, integration and regression

The verification testing activities performed, support the substantial equivalence determination of the subject Philips Intellisite Pathology Solution (PIPS) (K203845) with the modified Image Management System to the predicate Philips Intellisite Pathology Solution (PIPS) (K192259).

Cybersecurity

Security Threat analysis was performed for IMS version 4.1.1 and compared to previous version, IMS 3.2.1. No additional security risks were identified.

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.