Philips Medical Systems Nederland B.V.
Liselotte Kornmann
Associate Director Regulatory Affairs
Veenpluis 6
Best, Noord Brabant 5684PC
Netherlands

June 24, 2024

Re: K233204
Trade/Device Name: Philips IntelliSite Pathology Solution 5.1
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: PSY
Dated: September 28, 2023
Received: September 28, 2023

Dear Liselotte Kornmann:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shyam Kalavar -S

Shyam Kalavar
Deputy Branch Chief
Division of Molecular Genetics and Pathology
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233204

Device Name
Philips IntelliSite Pathology Solution 5.1

Indications for Use *(Describe)*
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. 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Philips IntelliSite Pathology Solution 5.1

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Preparation date: June 21, 2024

Company identification

Philips Medical Systems Nederland B.V.
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The Netherlands
Establishment registration number: 3012563754

Contact person

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Device

Device Trade Name: Philips IntelliSite Pathology Solution 5.1
Device Class: Class II
Product Code: PSY
Classification Regulation: 21 CFR, Part 864.3700
Classification Name: Whole Slide Imaging System
Classification Panel: Pathology
510(k) Submission Number: K233204

Predicate device

Device Trade Name: Philips IntelliSite Pathology Solution 5.1
510(k) Number: K203845 (September 17, 2021)

Device description

The Philips IntelliSite Pathology Solution (PIPS) 5.1 is an automated digital slide creation, viewing, and management system. PIPS 5.1 consists of two subsystems and a display component:

1. Subsystems:
    a. A scanner in any combination of the following scanner models
        i. Ultra Fast Scanner (UFS)
        ii. Pathology Scanner SG with different versions for varying slide capacity Pathology Scanner SG20, Pathology Scanner SG60, Pathology Scanner SG300
    b. Image Management System (IMS) 4.2
2. Display PP27QHD

Intended Use / Indications for Use

Compared to the predicate device, the Intended Use / Indications for Use of the subject device is updated to reflect the new Pathology Scanner models and IMS and is as follows:

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. 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.

Summary of Intended Use / Indications for Use

The difference between the subject and the predicate device does not alter the intended use of the device nor do they raise any new questions regarding safety or effectiveness. Both the subject and predicate devices have the same intended 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.

Summary of technological characteristics

The subject device employs the same technological characteristics compared to the currently marketed predicate device, with exception of the following modification implemented:

- Addition of a new Pathology Scanner SG with the following variants:
  - Pathology Scanner SG20
  - Pathology Scanner SG60
  - Pathology Scanner SG300
- Update of Image Management System 4.1 (IMS 4.1) to IMS 4.2 to support the previously cleared Ultra Fast Scanner (UFS) in K203854 and Pathology scanners SG20/SG60/SG300.
- The three pathology scanner SG models share the same imaging pipeline, which is implemented in the scan engine (Second Generation Scanner Engine-SGSE). Based on the System Design Specification documents, the differences between the three SG models are mainly the slide feeders and housing.

Comparison of technological characteristics

Item	**Predicate device PIPS (K203845)**	**Subject device PIPS 5.1 (K233204)**
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,	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,

Comparison of technological characteristics

Item	Predicate device PIPS (K203845)	Subject device PIPS 5.1 (K233204)
	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.	cytology, or non-FFPE hematopathology specimens. The PIPS 5.1 comprises the Image Management System (IMS) 4.2, the Ultra Fast Scanner (UFS), Pathology Scanner SG20, Pathology Scanner SG60, Pathology Scanner SG300 and PP27QHD 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.
Specimen type	Surgical pathology slides prepared from formalin-fixed, paraffin-embedded tissue	Same
Principle of operation	The technician loads the slides into the WSI scanner. The scanner scans the slides and generates WSI image for each slide. The technician performs Quality Control (QC) on scanned WSI images and rescan the slide when QC is failed. The acquired WSI images are stored in an end user provided image storage attached to the local network. During review, the pathologist opens WSI images acquired with the WSI scanner from the image storage, performs further QC and reads WSI images of the slides to make a diagnosis	Same
Device components	UFS, IMS and color monitor display	UFS, Pathology Scanner SG, IMS and color monitor display
Whole Slide Imaging Scanner	UFS with loading capacity of 300	UFS with loading capacity of 300 Pathology Scanner SG with loading capacity of 300, 60, 20
Image File Format	iSyntax	Same
End User's Interface	The IMS Image Processing Pipeline is designed to process UFS iSyntax data	The IMS Image Processing Pipeline is designed to process both UFS and Pathology Scanner SG iSyntax data
Monitor Display	PP27QHD	Same

The differences between the subject and the predicate device do not raise any new questions regarding safety or effectiveness. Based on the information provided above, the subject device PIPS 5.1 is substantially equivalent to the currently marketed predicate device (K203845) in terms of technological characteristics.

Performance Data

A. Summary of non-clinical performance data

Verification testing activities have been performed to support the substantial equivalence determination for the subject device PIPS 5.1 (including the new Pathology Scanner SG and modified IMS for Pathology Scanner SG support). Performance characteristics of the subject device PIPS 5.1 are equivalent to those of the predicate device PIPS (K203845).

1. Technical studies were conducted to evaluate the performance of the new Pathology Scanner SG and modified IMS for Pathology Scanner SG support, as recommended in FDA's guidance, *Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices*.

TPA item	Performance data description
Slide Feeder	Information was provided on the configuration of the slide feed mechanism, including a physical description of the slide, the number of slides in queue (carrier), and the class of automation. Information was provided on the user interaction with the slide feeder, including hardware, software, feedback mechanisms, and Failure Mode and Effects Analysis (FMEA).
Light Source	Descriptive information associated with the light source was provided. Testing information was provided to verify the spectral distribution of the light that is incident on the slide to the slide is to verify that the color reproducibility of the Pathology Scanner SG is within predefined limits. The tests passed their acceptance criteria.
Imaging optics	An optical schematic with all optical elements identified from slide (object plane) to image sensor (micro camera) was provided. Descriptive information regarding the microscope objective, auxiliary lens(es), and the magnification of imaging optics was provided. Testing information regarding the magnification, relative irradiance, optical distortions, and chromatic aberrations was provided. The tests passed their acceptance criteria.
Mechanical scanner Movement	Information and specifications on the configuration of the stage, method of movement, control of movement of the stage, and FMEA was provided. Test data to determine positioning accuracy and repeatability for the X-Y and Z stages was provided. The tests passed their acceptance criteria.
Digital Imaging sensor	Information and specifications on the sensor type, pixel information, responsivity specifications, noise specifications, readout rate, and digital output format were provided. Testing to determine the correct functioning of the digital image sensor. The tests passed their acceptance criteria.
Image Processing Software	Information and specifications on the exposure control, white balance, color correction, sub-sampling, pixel-offset correction, shading (flat-field) correction, and pixel-defect correction were provided.
Image composition	Information and specifications on the scanning method and focus, was provided. Test data to analyze the image composition performance was provided. The tests passed their acceptance criteria.
Image file formats	Information and specifications on the compression method, compression ratio, file format, and file organization were provided.
Image Review Manipulation Software	Information and specifications for continuous panning, continuous zooming, discrete Z-axis displacement, comparison of slides in multiple windows, annotation tools, image enhancement, color correction, tracking of visited areas, digital bookmarks, and shared viewing sessions was provided. Test data to analyze the image review manipulation software was provided. The tests passed their acceptance criteria.
Display	No changes have been introduced for the PP27QHD display. Tests results for this display in previous 510(k) remain valid.
Computer Environment	Information and specifications on the computer hardware, operating system, memory, hard disk, graphics card, graphics card driver, color management settings, color profile, display interface and network were provided.

TPA item	Performance data description
Color Reproducibility	Test data to quantify the accuracy and precision of the color transformation from the slide to the display monitor was provided. The tests passed their acceptance criteria
Spatial Resolution	Test data to evaluate the spatial resolution of the image acquisition phase was provided. The tests passed their acceptance criteria.
Focusing Test	Test data to demonstrate that the focus quality is clinically acceptable for a variety of histologic preparations, including different tissue types, stain intensities, specimen thicknesses, and stain types was provided. The tests passed their acceptance criteria.
Whole Slide Tissue Coverage	Test data to demonstrate that the entire tissue specimen on the clinical slide is detected by device was provided. The tests passed their acceptance criteria.
Stitching Error	Test data to evaluate the stitching quality of the high resolution image of the Pathology Scanner SG. The tests passed their acceptance criteria.
Turnaround Time	Test data to evaluate the average time required to execute zooming and panning operations, and to refresh the display in response to user input was provided. The tests passed their acceptance criteria.

2. Electrical safety testing was conducted in accordance with IEC61010-1 with passing results. Electromagnetic compatibility testing was conducted in accordance with IEC 61326-2-6 for laboratory use of in vitro diagnostic equipment with passing results. Electromagnetic compatibility testing was conducted in accordance with IEC 60601-1-2. The test results showed “pass” for emissions and immunity.

3. Human factors studies were designed around user tasks, and use scenarios performed by users were conducted. For all user groups, tasks were successfully completed.

3. **Pixelwise comparison with the predicate device:**
The equivalence between the subject device and the predicate device has been supported by bench testing data based on pixelwise comparison. A pixelwise comparison test has been performed to compare images reproduced by the predicate device and the subject device for the same iSyntax file to demonstrate identical image reproduction for UFS Images.
The subject device was tested as operating with the intended components, including the scanner, image management system and display.
Scanned images, on the predicate device, from 42 FFPE tissue glass slides from different anatomic locations were used as the test input. Three regions of interest (ROI) from each of the scanned images were selected. For each ROI, the differences between the views generated by the subject and predicate device were evaluated with the 1976 International Commission on Illumination (CIE) color difference metric ΔE for each corresponding pixel pair. Each location has been processed and sampled at 20x and 40x magnification level on both the predicate and subject device. The client workstation, according to device specification, with PP27QHD display has been used to capture ROIs and to perform the pixelwise comparison.
The color differences of all pixels within each ROI were reported. The image data of all ROIs were also provided for verification. The test results demonstrated that all image pairs are identical with zero ΔE. The subject device has been found to adequately reproduce digital pathology images at the pixel level with respect to its intended use.

B. Summary of analytical and clinical performance data

Two studies were conducted with the PIPS 5.1 device: Analytical studies to support device precision and clinical study to support the clinical performance of the device.

1. Precision study
Device precision was evaluated for its proposed intended use. The study was divided into the following three sub-studies:

- Scans from the same scanner (intra-system precision)
- Scans from different scanners at the same site (inter-system precision)
- Scans from different scanners located at different sites read by different pathologists (Inter-site reproducibility)

Intra-system study results

System	Number of Comparison Pairs	Number of Pairwise Agreements	Agreement Rate	
			%	95% CI
Overall	3600	3178	88.3	(86.7; 89.9)
Scanner 1	1210	1054	87.1	(84.1; 90.0)
Scanner 2	1190	1049	88.2	(85.6; 90.7)
Scanner 3	1200	1075	89.6	(86.6; 92.4)

Inter-system study results

Systems compared	Number of Comparison Pairs	Number of Pairwise Agreements	Agreement Rate	
			%	95% CI
Overall	3610	3445	95.4	(94.4; 96.5)
Scanner 1 – Scanner 2	1200	1144	95.3	(94.0; 96.6)
Scanner 1 – Scanner 3	1207	1152	95.4	(94.1; 96.7)
Scanner 2 – Scanner 3	1203	1149	95.5	(94.2; 96.7)

Inter-site study results

Sites compared	Number of Comparison Pairs	Number of Pairwise Agreements	Agreement Rate	
			%	95% CI
Overall	1228	1114	90.7	(88.4; 92.9)
Site 1 – Site 2	407	368	90.4	(87.5; 93.1)
Site 1 – Site 3	406	371	91.4	(88.5; 94.1)
Site 2 – Site 3	415	375	90.4	(87.5; 93.1)

The data show that the studies met the acceptance criterion of the lower limit of the 95% confidence interval (CI) of the Average Positive Agreement exceeding 85%.

2. Clinical Study:
A study was conducted to demonstrate that viewing, reviewing and diagnosing digital images of surgical pathology FFPE tissue slides using the PIPS 5.1 is non-inferior to using optical (light) microscopy. The primary endpoint was the difference in major discordance rates between manual digital (MD) and manual optical (MO) modalities when compared to the reference (main) diagnosis, which is based on the original sign-out diagnosis rendered at the institution, using an optical (light) microscope. By the study protocol, a total of 952 cases consisting of multiple organ and tissue types were to be enrolled. Cases were divided over three sites. In total 11 pathologists divided over three sites read all the cases assigned to the site using both the MO and the MD modalities in a randomized order and with a washout period of four weeks in between. Three adjudicators reviewed the reader diagnosis against the sign-

out diagnosis and determined whether the diagnosis was concordant, minor discordant or major discordant. After adjudication, the major discordance rate per modality was calculated.
The clinical study successfully met the primary endpoint of the study by demonstrating that viewing, reviewing, and diagnosing surgical pathology tissue slides by a pathologist supported by using PIPS 5.1 was non-inferior to using an optical microscope. The overall difference in major discordance rate (compared to the main diagnosis) for digital-optical was 0.1% with a 95% confidence interval of (-1.01%; 1.18%). As the upper limit of this confidence interval was less than the non-inferiority margin of 4%, manual digital diagnosis by a pathologist using the subject PIPS 5.1 is non-inferior to diagnosis by a pathologist using the optical microscope.

The acceptance criterion was as follows: The manual digital method would be declared non-inferior to the manual optical method if the upper bound of the 95% two-sided confidence interval for the manual digital – manual optical difference in major discordance rate is less than 4%.

Substantial equivalence conclusion

The subject PIPS 5.1 is substantially equivalent to the predicate device Philips IntelliSite Pathology Solution (K203845) in terms of Intended Use / Indications for Use, technological characteristics, and safety and effectiveness.
Non-clinical and clinical performance tests demonstrated that the modifications are properly introduced, and the device conforms to its intended use, users and use environment. These tests were used to support substantial equivalence of the subject device and demonstrated that it is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.