Philips Medical Systems Nederland B.V.
Donna Peled
Head of Regulatory Affairs - Clinical Informatics
Veenpluis 6
Best, 5684 PC
Netherlands

December 10, 2024

Re: K242848
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 20, 2024
Received: September 20, 2024

Dear Donna Peled:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K242848

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 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 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) SUMMARY

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

## 1.1 General information

December 02, 2024

### 1.1.1 Company identification

Philips Medical Systems Nederland B.V.
Veenpluis 6
5684 PC Best
The Netherlands
Registration number: 3012563754

### 1.1.2 Contact Person

Donna Peled
Head of Regulatory Affairs - Clinical Informatics
Digital & Computational Pathology
Phone: +972-52-6145353
Email: donna.peled@philips.com

### 1.1.3 Identification of the device and classification

Device trade name: Philips IntelliSite Pathology Solution 5.1
Device Class: Class II
Classification regulation: 864.3700
Product code: PSY
Classification name: Whole Slide Imaging System
Classification panel: Pathology
510K number: K242848

### 1.1.4 Legally marketed predicate devices to which substantial equivalence is claimed

Device trade name: Philips IntelliSite Pathology Solution 5.1
510(k) number: K233204 (June 24, 2024)
Device Class: Class II
CFR section: 864.3700
Product code PSY
Classification name: Whole Slide Imaging System
Classification panel: Pathology

## 1.2 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. A scanner in any combination of the following scanner models
   - Ultra Fast Scanner (UFS)
   - Pathology Scanner SG with different versions for varying slide capacity Pathology Scanner SG20, Pathology Scanner SG60, Pathology Scanner SG300
2. Image Management System (IMS) 4.2
3. Clinical display
   - PP27QHD or C411W

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.

## 1.3 Intended use

*Compared to the predicate device the Intended Use / Indications for Use statement of the subject device has been updated to reflect the new Beacon C411W display. The Intended use remains unchanged.*

*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 pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using PIPS 5.1.*

## 1.4 Comparison of technological characteristics with the predicate device

The proposed device has the same technological characteristics compared to the predicate device, with the exception of the following minor modification implemented in the proposed device: Introduction of a new clinical display, C411W, as an alternative option for the current display, PP27QHD.

The proposed device will employ display C411W from manufacturer Beacon as an option for the current display. The new display has similar technological characteristics and pixel resolution as

compared to the predicate device. Table below describes the modified technological characteristics for the new display in accordance with FDA's Guidance for Industry and FDA Staff entitled, "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices" (hereafter referred to as TPA Guidance), dated April 20, 2016.

Other TPA guidance items related to the display are not impacted by the new display and remain identical to the predicate device.

**Table 1.1 Modified technological characteristics for the display**

| **TPA Description** | | **Predicate device (K233204)** | **Proposed device** |
|---|---|---|---|
| Technological characteristics of the display device | Display type | Color LCD | Color LCD |
| | Manufacturer | Barco N.V. | Shenzhen Beacon Display Technology Co., Ltd |
| | Technology | IPS technology with a-Si Thin Film Transistor | Thin Film Transistor |
| | Physical display size | 648.5 mm x 423 mm x 91.3 mm (with backlight disc) | 646 mm x 423 mm x 91.3 mm |
| | Pixel Pitch | 0.2331 mm x 0.2331 mm | 0.2331 mm x 0.2331 mm |
| Color calibration tools (sensor hardware and associated software) | Calibration software | MediCal QAWeb Agent software version 1.13.12 installed on the workstation | Beacon QA Manager software version 1.1 installed on the workstation |
| | Calibration hardware | Built in front sensor | Built in front sensor |

## 1.5 Summary of non-clinical performance data

Non-clinical performance testing was performed on the display of the proposed device and demonstrates compliance with the following international and FDA-recognized consensus standards:

- 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

Following the TPA guidance, the below mentioned sub-set of tests were performed to verify that the technological characteristics of the display were not affected by the new panel.

- Spatial resolution
- Pixel defects
- Artifacts
- Temporal response
- Maximum and minimum luminance
- Grayscale
- Luminance uniformity

- Stability of luminance and chromaticity
- Bidirectional reflection distribution function
- Gray tracking
- Color scale response
- Color gamut volume.

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

**Conclusion**:
The verification for the new display showed that the proposed device has similar technological characteristics compared to the predicate device following the TPA guidance and is in compliance with aforementioned international and FDA-recognized consensus standards. Verification and validation of the existing safety, user and system integration requirements showed that the proposed PIPS 5.1 with the new clinical display is safe and effective. The proposed device conforms to its intended use and user needs. Therefore, the proposed device with the new clinical display is substantially equivalent to the predicate device in terms of safety and effectiveness.

## 1.6 Summary of clinical performance data

The proposed device with the new display did not require clinical performance data since substantial equivalence to the currently marketed predicate device was demonstrated with the following attributes:

- Intended Use / Indications for Use,
- Technological characteristics,
- Non-clinical performance testing, and
- Safety and effectiveness

These attributes demonstrated that the clinical performance of the modified device is substantially equivalent to the predicate device.

## 1.7 Conclusions

The proposed PIPS 5.1 with a new clinical display as option for the current display is substantially equivalent to the predicate device in terms of Intended Use/Indications for Use, technological characteristics, and safety and effectiveness.
The change of the display of the proposed device is within the controls and predetermined specifications. Additionally, non-clinical performance tests (bench testing) ensured that the modifications are properly introduced. These tests were used to support substantial equivalence of the proposed device and demonstrated that it is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.