October 4, 2017

Philips Medical Systems Nederland B.V.
Esther Abels
Director Regulatory, Clinical and Medical Affairs
Veenpluis 4-6
5684 PC, Best, NL

Re: K172174
Trade/Device Name: Philips IntelliSite Pathology Solution
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Class: Class II
Product Code: PSY
Dated: July 13, 2017
Received: July 19, 2017

Dear Esther Abels:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Yun-fu Hu -S

for Reena Philip, Ph.D.
Director
Division of Molecular Genetics and Pathology
Office of *In Vitro* Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172174

Device Name
Philips IntelliSite Pathology Solution

Indications for Use *(Describe)*
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.

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.

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510(K) SUMMARY

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

1 GENERAL INFORMATION

1.1 Preparation date

September 4, 2017

1.2 Company identification

Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684PC Best
The Netherlands
Registration number: 3003768277

1.3 Contact Person

Esther Abels
Director Regulatory, Clinical and Medical affairs
Philips Digital Pathology Solutions
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Email: esther.abels@philips.com

1.4 Identification of the device and classification

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

2 LEGALLY MARKETED PREDICATE DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

Device trade name: Philips IntelliSite Pathology Solution
De Novo number: DEN160056
Device Class: Class II
CFR section: 864.3700
Product code PSY
Classification name: Whole Slide Imaging System
Classification panel: Pathology

3 DEVICE DESCRIPTION

The Philips IntelliSite Pathology Solution (PIPS) is an automated digital slide creation, viewing, and management system. The PIPS consists of two sub-systems and a Display component:

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

PIPS 2.6.1 introduces one major change compared to the predicate device PIPS 2.5:

- New display PP27QHD:

The main changes between the previous and the new display are:
The dithering functionality is implemented on the display: The temporal and spatial dithering algorithm remains identical, i.e. no changes were made to the algorithm, but the implementation location has moved from the graphic board (PS27QHDCR) to the display itself (PP26QHD).
While predicate device PS27QHDCR was calibrated using a stand-alone sensor, the new display is calibrated using a build in front sensor. Calibrations and quality checks are initiated by the QAWeb agent and performed as a background activity. The user is informed by a small text box.

4 INTENDED USE

The intended use is unchanged compared to predicate device PIPS 2.5:
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.

5 TECHNOLOGICAL CHARACTERISTICS

The high level technological characteristics of the PIPS 2.6.1 are the same as the predicate device and are described below 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.
The TPA Guidance describes two subsystems of WSI devices: Image Acquisition and Workstation. The interface between the two subsystems is described as Image File Format component in the TPA Guidance.
The workstation as described in the TPA guidance maps to the Ultra Fast Scanner (UFS), which is able to scan tissue mounted on cover slipped glass slides to create high-quality, digital Whole Slide Images (WSI). The UFS consists of optical, mechanical and electronic elements as well as software components.
The Image Display subsystem as described in the TPA guidance maps to multiple subsystems/components within the PIPS architecture:

- Image Management System – This is a software only subsystem.
- Computer Environment – PIPS specifies compatible computer environment hardware and software for the customer. It is not included as part of the PIPS.
- Display – a display is included in the PIPS system.

Table 5.1 below describes the modified technological characteristics for the new display PP27QHD compared to the previous display PS27QHDCR as per TPA guidance.

There are no technological characteristics changes for the IMS nor for the UFS compared to the predicate device PIPS 2.5.

Table 5.1 Modified technological characteristics PP27QHD compared to PS27QHDCR

Item	Previous Display (PS27QHDCR)	New Display (PP27QHD)
Subpixel driving to improve grayscale resolution (e.g., spatial and temporal dithering)	Temporal dithering is applied on subpixel level over 256 frames. This temporal dithering is combined with spatial dithering in blocks of 64 x 64 pixels with 4096 different random values. The spatial dithering is optimized so that it can be tiled without visual effects.	The temporal and spatial dithering algorithm is identical to the previous device, i.e. no changes were made to the algorithm. The difference is that the temporal and spatial dithering is implemented in the medical display (PP27QHD) instead of in the graphics board (previous device). Images remain identical to the predicate device.
Supported color spaces	sRGB is supported	sRGB remains the default configuration. Additionally the following color spaces are supported but locked by default: -DICOM -Native
Display Interface	Display Port (DP) Universal Serial Bus (USB 2.0)	Additionally the following display interface is supported: -DVI-D Dual-link
Color calibration tools (sensor hardware and associated software), color profile, and method for color management	-Calibration software: Nucleus software installed on the workstation -Calibration hardware: Barco LCD sensor -Calibration target: sRGB with a target luminance of 350 cd/m2	-Calibration software: QAWeb Agent software installed on the workstation. The QAWeb agent implement the same calibration functions as the Nucleus software. -Calibration hardware: build in front sensor -Calibration target: unchanged
Frequency and nature of quality-control tests to be performed by the user and/or the physicist with associated action limits.	To perform a quality control test, the user places the Barco LCD sensor manually on the center of the screen and initiates the QA procedure. Philips recommends QA checks every 3 weeks.	The display is calibrated automatically using the built in front sensor. This sensor has similar performance compared to the Barco LCD sensor. The calibration is initiated by the QAWeb Agent software. Calibration and quality checks are performed in the background. The user is informed of the start and end of a calibration session and a QA session via a small balloon in the Windows system tray. By default QA check is performed weekly. These intervals are controlled by the QAWeb Agent calibration software. The most recent color calibration date and the status can be checked via the on-screen display. The actual display calibration status is always visible in the

Item	Previous Display (PS27QHDCR)	New Display (PP27QHD)
		Windows system tray: a green check indicates that the display is calibrated while a red cross indicates that the display is not calibrated.

6 BRIEF DISCUSSION ON NON-CLINICAL TESTS SUBMITTED, REFERENCES OR RELIED ON THIS PREMARKET NOTIFICATION

PIPS 2.6.1 complies with the following international and FDA recognized consensus standards, device specific guidance and special control:

- ISO 13485:2003
- ANSI/AAMI/ISO 15223-1
- ISO 14971:2012*
- IEC 62304:2006 (edition 1.0)
- IEC 62366-1:2015
- IEC 61010-1:2010
- IEC 61010-2-101:2015
- EN 61326-1:2013
- EN 61326-2-6:2013
- CLSI AUTO11-A:2014**
- ASTM D4169-16
- FCC Part 15
- FDA guidance “Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices”, April 20, 2016
- Special control for Whole Slide Imaging System as per classification order DEN160056.

*Note that compliance is claimed to version 2012 of the ISO 14971 standard that is not recognized by FDA. However, there is no difference in the normative text of the recognized and the claimed versions of the standard. Therefore the compliance matrix used to demonstrate compliance to ISO 14971:2012 could equivalently be used to claim compliance to ISO 14971:2007.
**Note that compliance is claimed to the version of the CLSI AUTO11-A standard that is not recognized by FDA. However, there is no difference in the normative text of the recognized and the claimed versions of the standard. Therefore, the compliance matrix used to demonstrate compliance to CLSI AUTO11-A:2014 could equivalently be used to claim compliance to CLSI AUTO11-A:2006.

Note that the PP27QHD display complies with the following international and FDA recognized consensus standards:

- EN 60601-1:2006 +A11:2011 +A1:2013 +A12:2014
- IEC 60601-1(ed.3), IEC 60601-1(ed.3);am1
- IEC 60601-1-2 (4th Ed)
- ANSI/AAMI ES60601-1:2005/(R)2012
- CSA CAN/CSA-C22.2 NO. 60601-1:14
- IEC 60529:1991 + A1: 2000 (Degrees of protection IP code)
- IEC 62471: 2006; EN 62471: 2008 (Photobiological Safety Of Lamps And Lamp System)
- IEC 60950-1:2005 (2nd Ed) Am1:2009 + Am2:2013
- FCC Part 15

The following verification and validation activities have been performed for PIPS 2.6.1:

- General verification testing: verification has been performed and covered testing of new and updated requirements (including risk control measures), integration and regression.
- In-house validation with user representatives: Each user was provided a Design Validation Survey that establishes the necessary conditions required for the proper assessment of each user need, followed by a series of survey questions related to the specific user need.

Conclusion: The verification and validation results for PIPS 2.6.1 comprising of verification testing and validation of the user needs are passed and support the safety and effectiveness of the product. It conforms to the intended use, the user needs and is therefore considered substantially equivalent to the currently marketed PIPS 2.5.

7 BRIEF DISCUSSION ON CLINICAL TESTS SUBMITTED, REFERENCES OR RELIED ON THIS PREMARKET NOTIFICATION

PIPS 2.6.1 did not require clinical studies to establish substantial equivalence to the predicate device PIPS 2.5. Substantial equivalence was demonstrated with the following attributes:

- Intended use / indications for use
- Technology and design features
- Safety and effectiveness

8 SUBSTANTIAL EQUIVALENCE CONCLUSION / CONCLUSIONS DRAWN FROM THE NONCLINICAL AND CLINICAL TESTS

PIPS 2.6.1 is substantially equivalent to the currently marketed predicate device PIPS 2.5 in terms of intended use/indications for use, technology and design features, and safety and effectiveness. The modifications of PIPS 2.6.1 are within the controls and predetermined specifications. Additionally, non-clinical performance tests provided in this 510(k) premarket notification demonstrated substantial equivalence to the predicate device and ensured that the modifications are properly introduced; verification and validation testing was conducted to ensure the proper introduction of the individual modifications listed. All of these components and tests were used to support substantial equivalence of the subject device and demonstrate that the PIPS 2.6.1 is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.