September 20, 2019

Liselotte Kornmann,
Sr. Regulatory Affairs Specialist
Philips Electronics Nederland B.V.
Veenpluis 6
5684 PC, Best
The Netherlands

Re: K192259
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: August 15, 2019
Received: August 21, 2019

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Soma Ghosh, Ph.D.
Chief
Division of Molecular Genetics
and Pathology
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

K192259

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.

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510(K) SUMMARY

This 510(k) Summary is prepared in accordance with 21 CFR §807.92.

General information

Preparation date

August 08, 2019

Company identification

Philips Electronics Nederland B.V.
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Contact person

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Identification of the device and classification

Device Trade Name: Philips IntelliSite Pathology Solution
Device Class: Class II
Product Code: PSY
Classification Regulation: 21 CFR, Part 864.3700
Classification Name: Whole Slide Imaging System
Classification Panel: Pathology

Predicate device

Device Trade Name: Philips IntelliSite Pathology Solution
Manufacturer: Philips Electronics Nederland B.V.
510(k) Number: K172174 (October 4, 2017)
Device Class: Class II
Product Code: PSY
Classification Regulation: 21 CFR, Part 864.3700
Classification Name: Whole Slide Imaging System
Classification Panel: Pathology

Device description

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

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

Intended use / Indications for Use

The Intended Use / Indications for Use of the proposed device is unchanged compared to the predicate device:

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.

Comparison of technological characteristics with the predicate device

The proposed device has the same technological characteristics compared to the predicate device, with exception of the following minor modification implemented in the proposed device: A new panel for display PP27QHD. The new panel has similar technological characteristics and pixel resolution as compared to the predicate device.

Table 5.1 below provides a comparison of the technological characteristics between the proposed device with the predicate device as per 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 items related to the display are not impacted by the new panel and remain identical to the predicate device.

Table 1 Comparison of technological characteristics with predicate device

TPA Description		**Predicate device (K172174)**	**Proposed device**
Technological characteristics of the display device	Panel type	Color LCD	Color LCD
	Manufacturer of Panel	Bi-Search Korea Inc./LG display Co., Ltd.	Innolux Corporation
	Technology	IPS technology with a-Si Thin Film Transistor	IPS technology with a-Si Thin Film Transistor
	Physical display size	648,5 mm x 423 mm x 91,3 mm (with backlight disc)	648,5 mm x 423 mm x 91,3 mm (with backlight disc)

The differences between the proposed device and the predicate device do not raise any new questions regarding safety or effectiveness. Based on the information provided in this 510(k) premarket notification, the proposed device is substantially equivalent to the currently marketed predicate device in terms of fundamental scientific technology and technological characteristics.

Summary of non-clinical performance data

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

- IEC 60601-1-2 (4th Ed)
- ANSI/AAMI ES60601-1:2005/(R)2012
- ISO 14971:2007 Medical devices – Application of risk management to medical devices
- IEC 62471: 2006; EN 62471: 2008 (Photobiological Safety Of Lamps And Lamp System)

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
- Temporal response
- Grayscale
- Luminance uniformity and Mura test
- Stability of luminance and chromaticity
- Specular and diffuse reflection coefficients
- Gray tracking
- Color scale response
- sRGB (standard Red Green Blue) color gamut

Conclusion:
The verification for the modified 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. The proposed device conforms to its intended use and user needs. Therefore, the proposed device with modified display is substantially equivalent to the predicate device in terms of safety and effectiveness.

Summary of clinical performance data

The proposed device with the new display panel 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.

Conclusions

The proposed PIPS with modified display is substantially equivalent to the predicate device in terms of Intended Use/Indications for Use, technological characteristics, and safety and effectiveness.
The modification in the display of the proposed device is within the controls and predetermined specifications. Additionally, non-clinical performance tests (verification 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.