DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 13, 2017

Philips Medical Systems Nederland B.V.
% Ms. Esther Abels
Director Quality & Regulatory and Medical Affairs
Veenpluis 4-6, Best, NL 5684 PC NB

Re: DEN160056
Philips IntelliSite Pathology Solution (PIPS)
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Classification: Class II
Product Code: PSY
Dated: November 29, 2016
Received: December 01, 2016

Dear Ms. Abels,

This letter corrects our letter sent April 12, 2017 and dated April 12, 2017.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Philips IntelliSite Pathology Solution (PIPS), a prescription device. The Philips IntelliSite Pathology Solution (PIPS) is indicated for use as follows:

> 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.
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> 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.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Philips IntelliSite Pathology Solution (PIPS), and substantially equivalent devices of this generic type, into class II under the generic name, "Whole Slide Imaging System."

FDA identifies this generic type of device as: **Whole Slide Imaging System.**

> The whole slide imaging system is an automated digital slide creation, viewing, and management system intended as an aid to the pathologist to review and interpret digital images of surgical pathology slides. The system generates digital images that would otherwise be appropriate for manual visualization by conventional light microscopy.

Section 513(f)(2) of the Food, Drug & Cosmetic Act (FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for de novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the FD&C Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the FD&C Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the FD&C Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On December 01, 2016, FDA received your *de novo* requesting classification of the Philips IntelliSite Pathology Solution (PIPS). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Philips IntelliSite Pathology Solution (PIPS) into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Philips IntelliSite Pathology Solution (PIPS) indicated for use as follows:

> 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.
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> 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.

can be classified in class II with the establishment of special controls for this type of device. FDA believes that the class II special controls identified later in this order, along with applicable

general controls, including the design controls under 21 CFR part 820, provide reasonable assurance of the safety and effectiveness of the device type. The identified risks to health and identified mitigations associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Identified Mitigations

Identified Risks to Health	Mitigation Measures
Inaccurate or missing results leading to, for example, incorrect diagnosis.	General controls and special controls (1) and (2)
Delayed results	General controls and special controls (1) and (2)

In combination with the general controls of the FD&C Act, a whole slide imaging system is subject to the following special controls:

(1) Premarket notification submissions must include the following information:

(i) The indications for use must specify the tissue specimen that is intended to be used with the whole slide imaging system and the components of the system.

(ii) A detailed description of the device and bench testing results at the component level, including for the following:

(A) Slide feeder;

(B) Light source;

(C) Imaging optics;

(D) Mechanical scanner movement;

(E) Digital imaging sensor;

(F) Image processing software;

(G) Image composition techniques;

(H) Image file formats;

(I) Image review manipulation software;

(J) Computer environment;

(K) Display system.

(iii) Detailed bench testing and results at the system level, including for the following:

(A) Color reproducibility;

(B) Spatial resolution;

(C) Focusing test;

(D) Whole slide tissue coverage;

(E) Stitching error;

(F) Turnaround time.

(iv) Detailed information demonstrating the performance characteristics of the device, including:

(A) Precision to evaluate intra-system and inter-system precision using a comprehensive set of clinical specimens with defined, clinically relevant histologic features from various organ systems and diseases. Multiple whole slide imaging systems, multiple sites, and multiple readers must be included.

(B) Reproducibility data to evaluate inter-site variability using a comprehensive set of clinical specimens with defined, clinically relevant histologic features from various organ systems and diseases. Multiple whole slide imaging systems, multiple sites, and multiple readers must be included.

(C) Data from a clinical study to demonstrate that viewing, reviewing, and diagnosing digital images of surgical pathology slides prepared from tissue slides using the whole slide imaging system is non-inferior to using an optical microscope. The study should evaluate the difference in major discordance rates between manual digital (MD) and manual optical (MO) modalities when compared to the reference (e.g., main sign-out diagnosis).

(D) A detailed human factors engineering process must be used to evaluate the whole slide imaging system user interface(s).

(2) Labeling compliant with 21 CFR 809.10(b) must include the following:

(i) The intended use statement must include the information described in paragraph (1)(i) of this section, as applicable, and a statement that reads, “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 this device.”

(ii) A description of the technical studies and the summary of results, including those that relate to paragraph (1)(ii) and (1)(iii) of this section.

(iii) A description of the performance studies and the summary of results, including those that relate to paragraph (1)(iv) of this section.

(iv) A limiting statement that specifies that pathologists should exercise professional judgment in each clinical situation and examine the glass slides by conventional microscopy if there is doubt about the ability to accurately render an interpretation using this device alone.

This device is subject to the premarket notification requirements under section 510(k) of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the whole slide imaging system they intend to market and receive clearance to market from FDA prior to marketing the device.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Nick Anderson at 301-796-4310.

Sincerely,

Reena Philip -S

Reena Philip, Ph.D.
Director
Division of Molecular Genetics and Pathology
Office of *In Vitro* Diagnostics and
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Center for Devices and
Radiological Health