SPECIAL 510(K): DEVICE MODIFICATION
OIR DECISION SUMMARY

510(k) Number: ____K192259_____

This 510(k) submission contains information/data on modifications made to the applicant's own class II or class I devices requiring 510(k). The following items are present and acceptable:

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1. The name and 510(k) number of the applicant's previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

   K172174

   Philips IntelliSite Pathology Solution

2. Applicant's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   The changes were for

   - New LCD panel for display PP27QHD
   - Implementation Unique Device Identification (UDI) in product labeling
   - SQL/Windows servers, review browser and viewer client application

   Verification and validation activities are performed for every change to Philips IntelliSite Pathology Solution. The verification and validation procedures, methods and acceptance criteria for product changes remain the same as those performed for and described in the predicate device, K172174.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device for technical performance characteristics of the display and operating system and programming language.

Item	Predicate device (K172174)	Subject device (K192259)
Device Name	Philips IntelliSite Pathology Solutio	Same

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, 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.	Same
LCD Panel technical characteristics	• Panel type: Color LCD • Technology: IPS technology with a-Si Thin Film Transistor • Physical display size: 648.5 mm x 423 mm x 91.3 mm (with backlight disc)	Same
LCD Panel manufacturer	Bi-Search Korea Inc./LG display Co., Ltd.	Innolux Corporation
SQL server	Microsoft SQL server 2008	Microsoft SQL server 2014
Windows server	Windows server 2008R2	Windows server 2012R2
Server processor architecture	Server software 32-bit	Server software 64-bit
Operating system	Windows 7, 8, 8.1 and 10	Unchanged
Review browser	Google Chrome and Internet Explorer	Google Chrome, Internet Explorer, Mozilla FireFox and Microsoft Edge
Viewer client application	Silverlight	HTML

5. A **Design Control Activities Summary** which includes:

   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis

   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

Risk assessments for LCD panel changes were performed to assess the impact and potential risks that may exist due to the new LCD panel for PP27QHD. The Risk Analyses took into account device hazards associated with the intended use of the device. This safety risk assessment did not reveal any new safety

risks or changes to existing safety risks for the display. The risk profiles remain identical and it was concluded that the display with new panel is safe to be used as a component of PIPS.

The following verification and validation studies were performed:

- Non-Clinical performance testing based on the outcome of the safety risk assessement and the test methods described in FDA Guidance "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices" issued April 20, 2016. The protocol, test methods and acceptance criteria used are the same as those used in predicate device submission K172174.
    - Safety testing
    - Testing of display device characteristics
        - 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

For each test, acceptance criteria were identified and observed results were compared to expected results. All acceptance criteria were met and all tests passed.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the applicant's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The applicant has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.