July 15, 2020

Jillian Sue, MS
Product Manager
Paige.AI, Inc.
11 Times Square, 37th Floor
New York, NY 10036

Re: K201005
Trade/Device Name: FullFocus
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Class: Class II
Product Code: QKQ
Dated: April 16, 2020
Received: April 16, 2020

Dear Jillian Sue:

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
Molecular Pathology and Cytology Branch
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

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)*
K201005

Device Name

FullFocus™

Indications for Use *(Describe)*

FullFocus™ is a software only device intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret, and manage digital images of pathology slides for primary diagnosis. FullFocus is not intended for use with frozen sections, cytology, or non-FFPE hematopathology specimens.

It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. FullFocus is intended for use with Philips Ultra Fast Scanner and monitor displays validated with verified test methods to meet required performance characteristics.

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
# FullFocus™

**Date Prepared:** July 15, 2020

**Submitter**

Paige.AI, Inc.
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**Contact Person**

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**Device**

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|---|---|
| Proprietary Name of the Device: | FullFocus |
| Classification Name: | Whole Slide Imaging System |
| Regulation Number: | 21 CFR 864.3700 |
| Product Codes: | QKQ |
| Device Class: | Class II |
| Review Panel: | 88 – Pathology |
| Common Name: | The FullFocus Viewer |

**Predicate Device**

| | |
|---|---|
| Proprietary/Trade Name: | Philips IntelliSite Pathology Solution (PIPS) |
| Submission Number: | DEN160056 |

**Device Description**

FullFocus is a web-based software-only device for viewing and manipulating digital pathology images of glass slides obtained from the Philips IntelliSite Pathology Solution (PIPS) Ultra Fast Scanner (UFS) on the monitor displays that are validated with verified test methods to meet required performance characteristics. FullFocus reproduces the whole slide images and is an aid to the pathologist to review, interpret and manage digital images of pathology slides for primary diagnosis.

The subject device is typically operated as follows:

1. The image acquisition is performed using the predicate device, PIPS UFS. The operator performs quality control of the digital slides per the instructions of PIPS UFS and lab specifications to determine if re-scans are necessary.

2. Once slide image is acquired using PIPS UFS, according to its Instructions for Use, and becomes available in scanner database file systems, a separate medical image communications software (not part of the device) will automatically initiate uploading the slide image and corresponding metadata to persistent cloud storage. Integrity checks are being performed at upload time when data is copied to storage.
3. The reading pathologist uses the subject device to select a case (patient), view the images and is able to perform the following actions, as needed:
    a. Zoom and pan the image
    b. Measure distances and areas in the image
    c. Annotate images

After viewing all images belonging to a particular case (patient), the pathologist will make a diagnosis.

FullFocus is compatible with:

- Monitor displays:
    - Barco PP27QHD
    - Philips PS27QHDCR
- FDA-cleared scanners:
    - Philips Ultra Fast Scanner
- Browsers:
    - Google Chrome
    - Microsoft Edge
    - Firefox

Additional monitor displays will be validated with verified test methods to meet required performance characteristics.

**Intended Use**

FullFocus is a software only device intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret, and manage digital images of pathology slides for primary diagnosis. FullFocus is not intended for use with frozen sections, cytology, or non-FFPE hematopathology specimens.

It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. FullFocus is intended for use with Philips Ultra Fast Scanner and monitor displays validated with verified test methods to meet required performance characteristics.

**Summary of Technological Characteristics**

| Item | Subject Device (K201005) | Predicate (DEN160056) |
|---|---|---|
| Device Trade Name | FullFocus | Philips IntelliSite Pathology Solution |
| Indications for Use | FullFocus is a software only device intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to | 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 |

| | | |
|---|---|---|
| | review, interpret, and manage digital images of pathology slides for primary diagnosis. FullFocus is not intended for use with frozen sections, cytology, or non-FFPE hematopathology specimens.<br><br>It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. FullFocus is intended for use with Philips Ultra Fast Scanner and monitor displays validated with verified test methods to meet required performance characteristics. | surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue.<br><br>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. |
| Specimen Type | Digitized surgical pathology slides prepared from FFPE tissue | Surgical pathology slides prepared from FFPE tissue |
| Image file format | iSyntax | Same |
| Image Manipulation Functions | Panning, zooming, color manipulation function, annotations, and measurements (distance & area) | Same |
| Type of Software Application | Internet browser-based application | Same |
| Device Components | FullFocus image viewing software | Ultra Fast Scanner (UFS), Image Management System (IMS), Display |
| Principle of Operation | After WSI images are successfully acquired by using PIPS UFS, the WSI images are stored in the cloud. During review, the pathologist opens WSI images from storage, perform further QC and reads WSI images of the slides to make a diagnosis. | After WSI images are successfully acquired by using PIPS UFS, the WSI images are stored in IMS Application Server & Storage software that is not provided as part of the PIPS, but may be located in a central server room separate from the workstation with the IMS viewing software and Display. During review, the pathologist opens WSI images from IMS Server & Storage, perform further QC and reads WSI images of the slides to make a diagnosis. |
| Image Storage | Images are stored in the cloud. | Images are stored in an end user provided image storage (PIPS IMS Application Server & Storage) attached to the local network |

| | | |
|---|---|---|
| End User's Interface | FullFocus | PIPS Image Management System (IMS) |

| Performance data | Description |
|---|---|
| Pixel-wise comparison | Based on pixel-wise comparison to PIPS, including zooming and panning operations across multiple tiles, FullFocus has been found to visually adequately reproduce digital pathology images to human readers with respect to its intended use. |
| Turnaround time | The system requirements have been fulfilled:<br>• When selecting a case, it should not take longer than 10 seconds until the image is fully loaded.<br>• When panning the image (one quarter of the monitor) it shall not take longer than 7 seconds until the image is fully loaded. |
| Measurements | Measurement accuracy has been verified using a test image containing objects with known sizes. |
| Human factors testing | FullFocus has been found to be safe and effective for the intended users, uses, and use environments. |

**Substantial Equivalence Comparison**

The major difference between the subject and predicate device is that the predicate device includes the Ultra Fast Scanner (UFS) and Philips PS27QHDCR monitor display, whereas the subject device is only the review software and indicated for use with the same scanner and monitor. The indications for use are slightly different since the PIPS Indication for Use includes the creation of digital images and FullFocus Indication for use solely describes viewing and managing those digital images.

When FullFocus is used with the PIPS UFS scanner and Philips PS27QHDCR monitor, the software has similar Indications for Use, Functional, and Technological Characteristics to the predicate Image Management System (IMS) application software and is therefore substantially equivalent to the predicate device (DEN160056).

**Summary of Studies**

**Non-clinical test results**

**Conducted per FDA's Guidance on Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices:**

Pixel-wise comparison study was conducted to compare color images reproduced by FullFocus and PIPS IMS. It was determined that color images reproduced by FullFocus were visually adequate with respect to its intended use.

Turnaround times for panning and zooming have been determined and found to be adequate for the intended use of the subject device.

The subject device has been found to perform accurate measurements with respect to its intended use.

**Conducted per FDA's Guidance on Applying Human Factors and Usability Engineering to Medical Devices:**

Task-based usability tests verified the FullFocus user interface to be intuitive, safe, and effective for the range of intended users.

**Conclusion:**

When FullFocus is used with the PIPS UFS scanner and PS27QHDCR monitor display, it has similar Indications for Use, Functional, and Technological Characteristics as the predicate IMS viewer application software. The results of non-clinical testing demonstrate the device is substantially equivalent to the PIPS (DEN160056).