510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I. Background Information:

A. 510(k) Number

K201005

B. Applicant

Paige.AI, Inc.

C. Proprietary and Established Names

FullFocus™

D. Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QKQ	Class II	21 CFR 864.3700	Pathology

II. Submission/Device Overview:

A. Purpose for Submission:

New device

B. Type of Test:

Not applicable – software-only device

III. Intended Use/Indications for Use:

A. Intended Use(s):

See Indications for Use below.

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

B. Indication(s) for Use:

For In Vitro Diagnostic 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.

C. Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV. Device/System Characteristics:

A. Device Description:

FullFocus (version 1.2.1) 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 renders the uploaded 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 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

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

Minimum System Requirements - Computer Environment
The system requirements are given in Tables 1 through 4 below.

Table 1: WSI scanner(s) that can be used with FullFocus

Manufacturer	**Model**
Philips Medical Systems Nederland B.V.	Ultra Fast Scanner (UFS)

Table 2: Monitors that can be used with FullFocus

Manufacturer	**Model**
Barco N.V.	PP27QHD
Philips	PS27QHDCR

Table 3: Computer environment minimum requirements for FullFocus

Computer Environment	**Minimum Requirements**
Hardware	Network bandwidth: 10 Mbps or above CPU: 2 cores, 1.6 GHz RAM: 4 GB
Software	Browsers: • Google Chrome (minimum version 83.0.4103.116) • Microsoft Edge (minimum version 44.18362.449.0) • Firefox (minimum version 72.0.2)

Table 4: Test methods to be used for evaluating additional monitors.

ID	**Specification**	**Minimum Requirement**	**Test method**
1	Warm-up Time	+/-1.25% / hour	IDMS 10.1
2	Resolution	MTF >35% at Nyquist	TG-18 4.5.4.1.1
3	Pixel defect	< 5 pixels	Visual assessment – Stuck ON and Stuck OFF per Defective Pixels (IDMS 7.6)
4	Gray tracking	+/- 0.02 delta-u'v'	AAPM Task Group 18 and 196 Reports

5	Color Temperature	<= 0.02 delta-u'v' (D65)	AAPM Task Group 196 report
6	Grayscale Function – Contrast Response Deviation	+/-20%	Contrast response deviation calculated by using TG-18 testing method for all 256 levels with the target model according to sRGB
7	Luminance max	>= 350 cd/m^2	Vantage-Point Suite of Measurement (IDMS 2.4)
8	Contrast ratio	>= 1000:1	Sequential Contrast (IDMS 5.10)
9	Color gamut	>= 99% sRGB	IDMS 5.18.1
10	Spatial luminance uniformity	< 20%	Vantage-Point Suite of Measurement (2.4) IDMS 8.1.2 Sampled Vantage Point Uniformity
11	Color error	< 4 dE_{00}	Measured using a spectrophotometer over the IEC61966-4 color patches using sRGB color space with D65 white point
12	Response time	<= 20ms	Response Time (IDMS 10.2.2) and Gray-to-gray Response time (IDMS 10.2.3) 9x9 points, equal lightness
13	Specular reflection coefficient	Specular < 2%	IDMS 11.7
14	Diffuse Reflection coefficient	Diffuse < 4%	IDMS 11.3.2

B. Instrument Description Information:

Modes of Operation	**Yes**	**No**
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   FullFocus™

2. Specimen Identification:

   The FullFocus uses digital pathology images obtained from the Philips IntelliSite Pathology Solution (PIPS) Ultra Fast Scanner (UFS) of Hematoxylin and Eosin (H&E) stained glass slides. The reading pathologist selects a case (patient) from a worklist external to the subject device whereby the subject device fetches the associated images from the external image storage. The scanned images are identified based on the previously assigned specimen identifier.

3. Specimen Sampling and Handling:

   Specimen sampling and handling are performed upstream and independent of the use of the subject device. Specimen sampling includes biopsy or resection specimens which are processed using histology techniques. The FFPE tissue section is H&E stained. Digital images are then obtained from these glass slides using the PIPS UFS.

4. Calibration:

   Not applicable

5. Quality Control:

   The subject device receives whole-slide images from the Paige (image) storage. All WSI files are quality-controlled images acquired from the scanner according the scanner's instructions for use. The subject device specific quality control measures are as follows:

   - View pathology images - Every pathologist should perform this test on review workstation before reading pathology images using the subject device to ensure that all scanned slide images have been imported and for every case, view the thumbnails in the pathology image window to verify that each slide that should be in the case is present (manually verifying tissue block and staining information from LIS).

   Additional details of the quality control procedures are provided in the device Instructions for Use.

V. Substantial Equivalence Information:

A. Predicate Device Name(s):

Philips IntelliSite Pathology Solution

B. Predicate 510(k) Number(s):

DEN160056

C. Comparison with Predicate(s):

Device & Predicate Device(s):	K201005	DEN160056
Device Trade Name	FullFocus™	Philips IntelliSite Pathology Solution
General Device Characteristic Similarities		
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.	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.
Specimen Type	Surgical pathology slides prepared from FFPE tissue (scanned digital images is the starting point)	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 applications	Same
General Device Characteristic Differences		
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)

VI. Standards/Guidance Documents Referenced:

1. Guidance for Industry "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices", dated April 20, 2016
2. Special controls under 21 CFR Sec. 864.3700 Whole slide imaging system
3. ISO 14971: Second Edition 2007-03-01 - Medical devices - Applications of risk management to medical devices
4. ANSI: AAMI IEC 62304: 2006/A1:2016 - Medical device software - Software life cycle processes
5. ANSI: AAMI IEC 62366-1:2015 - Medical devices - Part 1: Application of usability engineering to medical devices
6. AAMI TIR 45:2012 - Guidance on the use of AGILE practices in the development of medical device software

VII. Performance Characteristics (if/when applicable):

A. Analytical Performance:

1. Precision/Reproducibility:

   Not applicable

2. Linearity:

   Not applicable

3. Analytical Specificity/Interference:

   Not applicable

4. Accuracy (Instrument):

   Not applicable

5. Carry-Over:

   Not applicable

B. Other Supportive Instrument Performance Characteristics Data:

Technical performance testing for FullFocus device was performed. The new device was compared to the image management software component of the predicate device. The following testing was performed:

a. Pixel-wise comparison with the predicate device including zooming operations across multiple tiles and vertical/horizontal stitching seams
The equivalence between the subject and predicate image review manipulation software {IRMS, as defined in the FDA guidance titled "Guidance for Industry "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices", dated April 20, 2016 [TPA guidance, IV(A)(9)]} was evaluated by bench testing data based on pixel-level comparison. The subject IRMS was tested as operating with the intended components, including the scanner and monitor display to evaluate the pixel-wise differences. WSI files from 22 FFPE tissue glass slides from different anatomic locations that were H&E stained were used as the test input. For each region of interest (ROI), the differences between the views generated by the subject and predicate IRMS were evaluated with the International Commission on Illumination (CIE) color difference metric CIEDE2000 (ΔE) for each corresponding pixel pair. The two views generated by the subject and predicate IRMS were registered and cropped to find the maximum common areas. The test cases of ROIs included relevant biological features at magnification levels 20x and 40x. Horizontal/vertical stitching seams between the tiles were included in the ROIs when possible. The color differences of all pixel pairs within each ROI were reported. The image data of all ROIs were also provided for verification.

The test results demonstrated that the median ΔE values across all ROIs range from 0.80 ΔE to 3.85 ΔE with a median of 1.72 ΔE and mean of 1.85 ΔE (standard deviation: 0.67 ΔE). The mean ΔE values across all ROIs range from 0.89 ΔE to 4.58 ΔE with a median of 2.13 ΔE and mean of 2.24 ΔE (standard deviation: 0.81 ΔE). The median ΔE by browser and magnification was also reported and comparable to overall results.

The subject device has been found to visually adequately reproduce digital pathology images to human readers with respect to its intended use.

b. Turnaround Time for the image to be fully loaded while opening a slide from a medical device data system (MDDS) and for panning/zooming
The turnaround times for opening an image and panning have been measured in the subject device. The subject device has been found to have an acceptable turnaround time with respect to its intended use for opening the first image, and panning and zooming within the image.

c. Measurements – area and distance
Measurement accuracy has been verified using a test image containing objects of known sizes. The following set of tests were used to validate the measurement accuracy of the subject device.
- Measurements verified using calibration slide with known distances: An image of a calibration slide with known distances was used to verify the measurement accuracy of the subject device. Test results showed that the subject device performed accurate measurements with respect to its intended use.

d. Human Factors Testing
Human factors study designed around critical user tasks and use scenarios performed by representative users were conducted. A systematic evaluation of task-based usability including critical tasks required for operation of the device were evaluated at multiple sites using multiple users. All tasks associated with reviewing and reporting results for cases including confirmation that all slides belonging to specific cases are reviewed before reporting results, were included in the study. Overall, the results of the human factors testing were acceptable.

VIII. Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.