510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K210811

B Applicant

Inspirata, Inc.

C Proprietary and Established Names

Dynamyx Digital Pathology Software

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QKQ	Class II	21 CFR 864.3700 - Whole Slide Imaging System	PA - 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.

B Indication(s) for Use:

Dynamyx Digital Pathology Software is 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 and interpret these digital images for the purposes of primary diagnosis.

Dynamyx Digital Pathology Software is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens.

It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using Dynamyx Digital Pathology Software.

The Dynamyx Digital Pathology Software consists of the Installed Pathologist Client and the Pathologist Workstation Web Client. The Installed Pathologist Client is intended for use with Leica's Aperio AT2 DX scanner and Dell MR2416 monitor as well as Philips' Ultra Fast Scanner and Philips PP27QHD monitor. The Pathologist Workstation Web Clinent is intended for use with Philips Ultra Fast Scanner and Philips PP27QHD monitor.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

Dynamyx Digital Pathology Software is a client-server software device used for importing, displaying, navigating, and annotating whole slide images obtained from the Leica Aperio AT2 DX scanner or the Philips IntelliSite Pathology Solution (PIPS) Ultra-Fast Scanner (UFS).

Whole slide images are created by scanning glass microscope slides using a digital slide scanner which are then imported into the Dynamyx Digital Archive server. Dynamyx uses the image decoding libraries licensed by Leica and Philips for the native images. Dynamyx then uses lossless compression to send the image to the Dynamyx viewers.

Whole slide images are viewed in the Dynamyx image viewer window by pathologists for the purposes of making a primary diagnosis. The pathologist can also navigate (pan and zoom) and annotate the images.

Dynamyx incorporates typical histology/pathology workflow and is operated as follows:

1. The subject device receives whole slide images from the scanner and extracts a copy of the images' metadata. The unaltered images are then sent to the external image storage (Digital Archive). A copy of the image metadata (e.g., the pixel size) is stored in the subject device's database to increase the operational performance (e.g., response times) of Dynamyx.
2. Whole slide images are reviewed first by the scanning technician such as a histologist to confirm image quality and initiate any slide rescans as necessary prior to being viewed by pathologists. The digital slide review quality control (QC) status determined by the scanning technician indicates which whole slide images have been reviewed and have passed QC. The QC status is available to the reading pathologist.

3. The reading pathologist selects a patient case from a selected worklist within Dynamyx whereby the case images are retrieved from the digital archive.
4. The reading pathologist uses Dynamyx to view and perform the following actions on the displayed image:
    a. Zoom and pan the image
    b. Adjust the apparent image observed magnification level
    c. Measure distances and areas
    d. Annotate images and cases
5. The above steps are repeated as required.

After viewing all images, the pathologist will render a diagnosis which is documented in a laboratory information system.

Minimum System Requirements - Computer Environment
The system requirements are given in Tables 1 through 2d below.

Table 1: WSI scanners and displays that can be used with Dynamyx Digital Pathology Software

Manufacturer	Model
Philips Medical Systems Nederland B.V.	Scanner: Ultra-Fast Scanner (UFS)
	Display: MMPC-4127F1/PP27QHD
Leica Biosystems Imaging, Inc.	Scanner: Aperio AT2 DX Slide
	Display: MR2416 (Dell)

Note: Philips PP27QHD monitor must be used with Philips Ultra-Fast Scanner and Dell MR2416 monitor must be used with Leica Aperio AT2 DX Scanner. The monitors are not interchangeable.

Table 2a: Computer environment minimum requirements for Dynamyx Digital Pathology Software, Dynamyx Server

	Server	vCPU	Memory	Drives
Hardware	Workflow Server	2 cores	Total - 8 GB	C Drive - 200 GB
	SQL Server	2 cores	Total - 8 GB	C Drive - 200 GB E Drive - 600 GB F Drive - 600 GB
	Digital Archive Server	8 cores	Total - 16 GB	C Drive - 200 GB E Drive - 200 GB F Drive - Image Store (Drive of appropriate size)
	Web Server	2 cores	Total - 8 GB	C Drive - 200 GB E Drive - 25 GB
	Job Agent Server	4 cores	Total - 8 GB	C Drive - 200 GB

	Component	Version	Comments
Software	Database	SQL Server 2016 or 2019	Latest patches recommended

Table 2b: Computer environment minimum requirements for Dynamyx Digital Pathology Software, Histology Workstation

	Component	Specifications/Application	Comments
Hardware	Processor	Intel i5 or greater	N/A
	Memory	8 GB RAM	N/A
	Internal Storage	7200 RPM or faster disks or SSD	Space requirements are nominal (<10GB)
	Network Connectivity	100 Mbps Full Duplex	1Gbps preferred
	Video Adapter	Web GL compatible	N/A
	Display	If Leica scanner, then use Dell MR2416 display If Philips scanner, then use PP27QHD display	Required for Image QC review
Software	Operating System	Windows 10	Latest patches recommended

Table 2c: Computer environment minimum requirements for Dynamyx Digital Pathology Software, Pathology Workstation (Web based)

	Component	Specification/Application	Comments
Hardware	Processor	Intel i5 or greater	N/A
	Memory	8 GB RAM	N/A
	Internal Storage	N/A	N/A
	Network Connectivity	100 Mbps Full Duplex	N/A
	Video Adapter	Web GL compatible	N/A
	Display	If Leica scanner, then use Dell MR2416 display If Philips scanner, then use PP27QHD display	Required for Diagnostic Use (Dx)
Software	Operating System	Windows 10	Latest patches recommended
	Browser	Chrome	Latest version of browser is recommended

Table 2d: Computer environment minimum requirements for Dynamyx Digital Pathology Software, Pathology Workstation (installed)

	Component	Specification	Comments
Hardware	Processor	Intel i5 or greater	N/A
	Memory	8 GB RAM	N/A
	Internal Storage	7200 RPM or faster disks or SSD	Space requirements are nominal (<10GB)
	Network Connectivity	100 Mbps Full Duplex	1Gbps preferred
	Video Adapter	Web GL compatible	N/A
	Display	If Leica scanner, then use Dell MR2416 display If Philips scanner, then use PP27QHD display	Required for Diagnostic Use (Dx)
Software	Operating System	Windows 10	Latest patches recommended

B Instrument Description Information:

1. Instrument Name:

   Dynamyx Digital Pathology Software

2. Specimen Type:

   Surgical pathology slides prepared from FFPE tissue

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 them obtained from these glass slides using the PIPS UFS or Leica Aperio AT2 DX Slide Scanner.

4. Calibration:

   Not applicable

5. Quality Control:

   When used as part of the Philips IntelliSite Pathology Solution (PIPS) system, the following QC procedure is used: The scanning technician views slide macro images on the Philips'

Ultra-Fast Scanner interface to confirm all tissue is contained in the scanned area and then uses the Dynamyx Digital Pathology Software to confirm the scanned image quality (e.g., focus, color, stitch errors, missing tissue). The QC status is available to pathologist.

When used with the Leica Aperio AT2 DX System, the following QC procedure is used: The scanning technician views the slide macro image on the Leica system's interface to confirm all tissue is contained in the scanned area and then uses the Dynamyx Digital Pathology Software to confirm the scanned image quality (e.g., focus, color, stitch errors, missing tissue). The QC status is available to pathologist.

Refer to the Dynamyx Digital Pathology Software user guide for additional information.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Philips IntelliSite Pathology Solution (PIPS)
Aperio AT2 DX System

B Predicate 510(k) Number(s):

DEN160056
K190332

C Comparison with Predicate(s):

Device & Predicate Device(s):	**K210811**	**DEN160056**	**K190332**
Device Trade Name	Dynamyx Digital Pathology Software	Philips IntelliSite Pathology Solution (PIPS)	Leica Aperio AT2 DX System
General Device Characteristics: Similarities			
Intended Use/ Indications For Use	Dynamyx Digital Pathology Software is 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	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	The Leica Aperio AT2 DX System is an automated digital slide creation and viewing system. The Leica Aperio AT2 DX System 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

	and interpret these digital images for the purposes of primary diagnosis. Dynamyx Digital Pathology Software is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using Dynamyx Digital Pathology Software. The Dynamyx Digital Pathology Software consists of the Installed Pathologist Client and the Pathologist Workstation Web Client. The Installed Pathologist Client is intended for use with Leica's Aperio AT2 DX scanner and Dell MR2416 monitor as well as Philips' Ultra Fast Scanner and Philips PP27QHD monitor. The Pathologist Workstation Web Clinent is intended for use with Philips' Ultra Fast Scanner and Philips PP27QHD monitor.	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.	paraffin embedded (FFPE) tissue. The Leica Aperio AT2 DX System is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. The Leica Aperio AT2 DX System is composed of the Leica Aperio AT2 DX scanner, the ImageScope DX review application and Display. The Leica Aperio AT2 DX System 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 the Leica Aperio AT2 DX System.
Specimen Type	Surgical pathology slides prepared from FFPE tissue	Same	Same
Image Storage	Images are stored in end user provided image storage attached to the local network	Same	Same
Image Manipulation Functions	Panning, zooming, image adjustments, annotations, and distance/area measurements	Same	Same
Image Review and Diagnosis	During review, the pathologist opens WSI	Same	Same

	images acquired with the WSI scanner from the image storage, performs further QC and interprets the WSI images to make a diagnosis		
Diagnostic Status of Images	Displays a visual indicator for the diagnostic status of an image	Same	Same
User Interface	Full-featured image viewer with integrated case list containing slide thumbnails	Same	Same
General Device Characteristic: Differences			
Device Components	Dynamyx digital pathology software	Ultra-Fast Scanner (UFS), Image Management System (IMS), Display	Aperio AT2 DX scanner, the ImageScope DX review application and Display

VI Standards/Guidance Documents Referenced:

1. Guidance for Industry "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices", dated April 20, 2016
2. ANSI AAMI IEC 62304:2006 & A1:2016 - Medical device software - Software life cycle processes
3. ANSI AAMI IEC 62366-1:2015+AMD1:2020 – Application of usability engineering to medical devices
4. ANSI AAMI ISO 14971: 2019 – Applications of risk management to medical devices
5. 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 Dynamyx Digital Pathology Software device was performed. The new device was compared to the Image Management Software (IMS) component of the Philips PIPS device and the ImageScope DX viewer software of Leica Aperio AT2 DX System. The following testing was performed:

a. Pixel-wise comparison with the predicate device including zooming and panning operations

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 supported by bench testing data based on pixel-level comparison. The subject IRMS was tested as operating with the intended components, including the scanner, image management system and display. Scanned images from 33 FFPE tissue glass slides from different anatomic locations 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 1976 International Commission on Illumination (CIE) color difference metric ΔE for each corresponding pixel pair. The two views generated by the subject and predicate IRMS were adjusted and registered by using only the graphical user interface without image processing. The test cases of ROIs included relevant biological features at different magnification levels such as 40x, 20x and 10x. Horizontal/vertical stitching seams between the tiles were included in the ROIs when possible.

Sixty image pairs at 40x, 20x, and 10x were used to test Dynamyx Digital Pathology Software Installed Pathologist Client against the predicate Leica AT2 DX. Similarly, sixty image pairs at 40x and 20x were used to test Dynamyx Digital Pathology Software Installed Pathologist Client against the predicate Philips PIPS. In addition, sixty image pairs at 40x and 20x were used to test Dynamyx Digital Pathology Software Pathologist Workstation Web Client running in the Chrome browser against Philips PIPS.

The color differences of all pixels within each ROI were reported. The image data of all ROIs were also provided for verification. The test results demonstrated that all image pairs are identical with zero ΔE. The subject device has been found to adequately reproduce digital pathology images at the pixel level with respect to its intended use.

b. Turnaround Time

Turnaround time test was performed to verify the streaming indicator functionality and to measure the turnaround time for initial image load, panning via mouse drag and zooming with 10 concurrent users using Leica Aperio AT2 DX scanner images and Philips UFS images. Test results are acceptable.

c. Measurement Accuracy

Measurement accuracy testing was performed to verify the calculated measurement for each annotation (e.g., length and area) is accurate to within 5% of the reference measurement using a certified micron scale image created using a Leica Aperio AT2 DX scanner and a Philips UFS. Test results showed that the subject device performed accurate measurements with respect to its intended use.

d. Human Factors (Usability) Testing

Formative and summative usability testing was conducted on the Dynamyx Pathology Workstation and the Histologist Workstation interfaces in accordance with FDA Guidance on "Applying Human Factors and Usability Engineering to Medical Devices.

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.