March 01, 2022

Inspirata, Inc.
Richard Morroney
Director of Regulatory Compliance
One North Dale Mabry Hwy
Suite 600
Tampa, FL 33609

Re: K210811
Trade/Device Name: Dynamyx Digital Pathology Software
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: QKQ
Dated: December 15, 2021
Received: December 16, 2021

Dear Richard Morroney:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210811

Device Name
Dynamyx Digital Pathology Software

Indications for Use *(Describe)*

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 Client is intended for use with Philips' Ultra Fast Scanner and Philips PP27QHD monitor.

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.

6.0 510(k) Summary

Date Prepared: February 28, 2022

Submitter: Inspirata, Inc.
One North Dale Mabry Hwy
Suite 600
Tampa, FL 33609

Contact Person: Richard Morroney, RAC, CQA
Director of Regulatory Compliance
Phone: (813) 570-8900
Fax: (813) 570-8901

Submission Date: March 15, 2021

Device Identification

Proprietary/Trade Name:	Dynamyx Digital Pathology Software
Classification Name:	Whole Slide Imaging System
Regulation Number:	21 CFR 864.3700
Product Code:	QKQ
Device Classification:	Class II
Review Panel:	88 – Pathology
Common Name:	Digital Pathology Image Viewing and Management Software

Predicate Device Identification

Proprietary/Trade Name	Leica Aperio AT2 DX System	Philips IntelliSite Pathology Solution (PIPS)
510(k) Number	K190332	DEN160056
Clearance Date	May 20, 2019	April 12, 2017
Classification Name	Whole Slide Imaging System	
Regulation Number	21 CFR 864.3700	
Product Code	PSY	
Device Classification	Class II	
Review Panel	88 – Pathology	
Common Name	Digital Pathology Whole Slide Imaging System	

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 Ultra Fast Scanner.

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 images to the Dynamyx viewer.

Note that Dynamyx has two different applications for two different inputs as specified below.

1. The Dynamyx Web Application running in the Chrome browser can only display WSI from the Philips Ultra Fast Scanner.

2. The Dynamyx Installed Client Application can display WSI from both the Leica AT2 DX Scanner and the Philips Ultra Fast Scanner.

Whole slide image files are viewed in the Dynamyx image viewer window by histologists and by pathologists who can also navigate (pan and zoom) and annotate the images.

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

1. Dynamyx receives whole slide images from the scanner as specified above 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. Depending upon a laboratory's workflow, whole slide images may be reviewed first by histologists to confirm image quality and initiate any slide rescans as necessary prior to being viewed by pathologists. The digital slide review QC status determined by the histologist indicates which slides have been reviewed and approved. 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, navigate, annotate, and interpret the digital images. The pathologist can perform the following actions to displayed image:
    a. Zoom and pan the image at will;
    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 make a diagnosis which is documented in a laboratory information system.

Intended Use Statement

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 Client is intended for use with Philips' Ultra Fast Scanner and Philips PP27QHD monitor.

Summary of Technological Characteristics

Item	Subject Device Dynamyx	Predicate Device Philips IntelliSite Pathology Solution (PIPS) DEN160056	Predicate Device Leica Aperio AT2 DX System K190332
Similarities			
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 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 Client is intended for use with Philips' Ultra Fast Scanner and Philips PP27QHD monitor.	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-fix 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.	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 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.

Item	Subject Device Dynamyx	Predicate Device Philips IntelliSite Pathology Solution (PIPS) DEN160056	Predicate Device Leica Aperio AT2 DX System K190332
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 images acquired with the WSI scanner from the image storage, performs further QC and interprets the WSI images to make a diagnosis.	Same	Same
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
Display Monitor	Dynamyx does not include a monitor but is indicated for use with the Dell MR2416, and Philips PP27QHD monitor with each system respectively.	Philips PP27QHD	Dell MR2416

Item	Subject Device Dynamyx	Predicate Device Philips IntelliSite Pathology Solution (PIPS) DEN160056	Predicate Device Leica Aperio AT2 DX System K190332
Performance Testing	• Color Reproducibility • Turnaround Time • Measurement Accuracy • Usability	Same	Same

Item	Subject Device Dynamyx	Predicate Device Philips IntelliSite Pathology Solution (PIPS) DEN160056	Predicate Device Leica Aperio AT2 DX System K190332
Differences			
Image QC	When used as part of the Philips system, image QC is embedded in workflow. Scan techs view slide macro images on the UFS interface to confirm all tissue is contained in the scanned area. Users view the images to confirm scan quality using the Dynamyx viewer. QC status available to pathologist. When used as part of the Leica Aperio system, image QC is embedded in workflow. Scan techs view slide macro images on the AT2 DX interface to confirm all tissue is contained in the scanned area. Users view the images to confirm scan quality using the Dynamyx viewer. QC status available to pathologist.	Image QC embedded in workflow. Scan techs view slide macro images on the UFS interface to confirm all tissue is contained in the scanned area. Users view the images to confirm scan quality using the IMS Viewer.	Image QC embedded in workflow. Scan techs view slide macro images on the AT2 DX interface to confirm tissue is contained in the scanned area. Users view the images to confirm scan quality using the ImageScope DX viewer.

Item	Subject Device Dynamyx	Predicate Device Philips IntelliSite Pathology Solution (PIPS) DEN160056	Predicate Device Leica Aperio AT2 DX System K190332
Differences			
User Interface	Dynamyx is a stand-alone medical device software.	The Image Management System (IMS) software is an integrated component of the PIPS.	Leica Aperio ImageScope DX viewer software is an integrated component of the AT2 DX system.
Microscope Slide Scanner	Dynamyx is a software only device and does not include any hardware or scanner. However, it is indicated for use with the Leica Aperio AT2 DX Scanner and the Philips UFS.	Philips Ultra Fast Scanner (UFS)	Leica Aperio AT2 DX Slide Scanner
WSI Display Input	Dynamyx has two applications for two different inputs. 1. The Dynamyx Web Application running in the Chrome browser can only display WSI from the Philips Ultra Fast Scanner. 2. The Dynamyx Installed Client Application can display WSI from both the Leica AT2 DX Scanner and the Philips Ultra Fast Scanner.	The IMS viewer is browser based and can display only .iSyntax WSI files	ImageScope viewer is an installed application and can only display .svs WSI files

Substantial Equivalence Comparison

The major difference between the predicate devices and Dynamyx is that the predicate devices are comprised of a system of hardware and software components, whereas Dynamyx is indicated for use with the same scanners and monitors. Therefore, the predicate device indications for use are slightly different to account for the creation of digital images whereas Dynamyx is intended as a replacement software component used for viewing and management of those images.

Dynamyx has two different applications for two different inputs as specified below.

1. The Dynamyx Web Application running in the Chrome browser can only display WSI from the Philips Ultra Fast Scanner.

2. The Dynamyx Installed Client Application can display WSI from both the Leica AT2 DX Scanner and the Philips Ultra Fast Scanner.

The IMS viewer is browser-based and can display only .iSyntax WSI files. The ImageScope viewer is an installed application and can only display .svs WSI files.

The AT2 DX scanner provides a color-coded status indication on the scanner control panel showing whether or not the scanner was able to focus on the tissue being scanned. The status colors are not an absolute indicator of image quality. They are used as a diagnostic tool alerting the user of possible problems with a scan. This scanner feature is independent of the viewer. The AT2 DX user manual states that regardless of the scan status color, all slides should be reviewed for acceptable image quality. Thus, digital slide image QC is performed using the image viewer.

The Ultra Fast Scanner provides a user interface where macro images of the scanned slide can be viewed to confirm that all the slide tissue was scanned. Digital slide image QC is performed using the Philips IMS viewer. The IMS user manual states that before a slide is used for diagnosis, the pathologist must check the image to ensure that it is suitable for diagnosis.

Using the Dynamyx viewer, a histotechnologist can review the quality of digital slide images and can assign the QC status of the images as rescan or reviewed/approved. The slide image review status (i.e., scan quality is approved or not approved) is available to the pathologist. Ultimately, it is up to the pathologist to look at digital slide images to verify they are of sufficient quality to perform their task.

Both predicate devices have the ability to confirm scan quality, i.e., check for missing tissue and faint tissue at the scanner. Although Dynamyx does not include a scanner, that doesn't preclude these checks from being performed. Additionally, the check for missing or faint tissue can be performed using the Dynamyx viewer. Both the predicates and Dynamyx require an equivalent manual review of image quality. Therefore, these differences indicate that Dynamyx software does not introduce any new potential safety or efficacy issues.

The Dynamyx Digital Pathology Software when used with the Leica Aperio AT2 DX

scanner / Dell MR2416 monitor and the Philips UFS scanner / PP27QHD monitor have similar indications for use, functional and technological characteristics as the ImageScope DX viewer and Philips IMS Viewer of the predicate devices and is therefore substantially equivalent to the Leica predicate device (K190332) and the Philips predicate device (DEN160056).

Summary of Non-Clinical Performance Testing:

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, Usability Engineering procedure and the Risk Management Process.

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.

Summary of Clinical Performance Data:

Clinical study results are not required for a substantial equivalence determination. Therefore, this submission contains no clinical study information.

Conclusion:

The Dynamyx Digital Pathology Software when used with the Leica Aperio AT2 DX scanner / Dell MR2416 monitor and the Philips Ultra Fast Scanner / Philips PP27QHD monitor, has similar indications for use, functional, and technological characteristics as the ImageScope DX viewer application and the IMS Viewer software of the predicate devices. The results of non-clinical testing demonstrate that the subject device is safe and effective and substantially equivalent to the Leica Aperio AT2 DX (K190332) and Philips PIPS (DEN160056) predicate devices.