PathAI, Inc.
Carrene Plummer
Head of Regulatory Affairs
1325 Boylston Avenue
Suite 10000
Boston, MA 02215

June 26, 2025

Re: K243391
Trade/Device Name: AISight Dx
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: QKQ
Dated: October 31, 2024
Received: November 1, 2024

Dear Carrene Plummer:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shyam Kalavar -S

Shyam Kalavar
Deputy Branch Chief
Division of Molecular Genetics and Pathology
OHT7: Office of In Vitro Diagnostics
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)*
K243391

Device Name
AISight Dx

Indications for Use *(Describe)*
For In Vitro Diagnostic Use

AISight Dx 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 these slides for primary diagnosis. AISight Dx 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. AISight DX is intended to be used with interoperable displays, scanners and file formats, and web browsers that have been 510(k) cleared for use with the AISight Dx or 510(k)-cleared displays, 510(k)-cleared scanners and file formats, and web browsers that have been assessed in accordance with the Predetermined Change Control Plan (PCCP) for qualifying interoperable devices.

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.

510(k) Summary
AISight Dx

DATE PREPARED: June 25, 2025

SUBMITTER/510(k) HOLDER

PathAI, Inc.
1325 Boylston Avenue
Boston, MA 02215

Primary Contact Person:
Carrene Plummer
Head of Regulatory
Telephone (520) 405-1462

DEVICE

Proprietary Name:	AISight Dx
Viewer Version:	V 2.9
Classification Name:	Whole Slide Imaging System
Regulation Number:	21 CFR 864.3700
Product Code:	QKQ
Regulatory Classification:	Class II
Review Panel:	88 - Pathology
Common Name:	Digital Pathology Image Viewing and Management Software
Submission Number:	K243391

PREDICATE DEVICES

Proprietary Name:	NanoZoomer S360MD Slide scanner system
Submission Number:	K233027

Proprietary Name:	Aperio GT 450 DX
Submission Number:	K232202

INDICATIONS FOR USE

For In Vitro Diagnostic Use

AISight Dx 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 these slides for primary diagnosis. AISight Dx 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. AISight DX is intended to be used with

interoperable displays, scanners and file formats, and web browsers that have been 510(k) cleared for use with the AISight Dx or 510(k)-cleared displays, 510(k)-cleared scanners and file formats, and web browsers that have been assessed in accordance with the Predetermined Change Control Plan (PCCP) for qualifying interoperable devices.

DEVICE DESCRIPTION

AISight Dx is a web-based, software-only device that is intended to aid pathology professionals in viewing, interpretation, and management of digital whole slide images (WSI) of scanned surgical pathology slides prepared from formalin-fixed, paraffin-embedded (FFPE) tissue obtained from Hamamatsu NanoZoomer S360MD Slide scanner or Leica Aperio GT 450 DX scanner (Table 1). It aids the pathologist in the review, interpretation, and management of pathology slide digital images used to generate a primary diagnosis.

Table 1: Interoperable devices of AISight Dx

Scanner	**Scanner Output File format**	**Viewing Software**	**Display**
Leica Aperio GT 450 DX	SVS, DICOM	AISight Dx	Barco MDPC8127 Dell UP3017 Dell U3023E Dell U3223QE JVC Kenwood JD-C24BN01A
Hamamatsu S360MD Slide scanner	NDPI		

AISight Dx is operated as follows:

1. A lab technician prepares and scans slides onto the WSI scanner. Once the image is acquired, the technician reviews slide quality in accordance with the WSI scanner's quality control process and standard lab procedures.
2. The AISight Dx workflow is initiated when the WSI from the scanner is ingested into the AISight Dx image management system via one of the supported ingestion methods: manual upload, bulk ingestion, or LIS ingestion.
3. The reading pathologist selects a case from the dashboard or case management page. The accession then opens in the slide viewer page for assessment.
4. The reading pathologist uses AISight Dx to view and interpret the images including, but not limited to, the following features:
    - Zoom and pan the image
    - Measure distances and areas in the image
    - Annotate the image
    - View multiple images side by side
5. The above steps are repeated as needed for all WSIs that apply to the case.
6. After viewing all images for the case, the pathologist will make a diagnosis. The diagnosis will be entered by the pathologist and transferred to the laboratory's reporting system, e.g., a Laboratory Information System (LIS).
7. After case diagnosis is completed by the pathologist, the case workflow is terminated by clicking "Finalize" in AISight Dx.

Quality Control:

Prior to using a WSI for diagnosis, it is the responsibility of the laboratory staff, while scanning glass slides and uploading WSIs, and the pathologist, while reviewing the WSIs, to ensure that all scanned slide images have been imported for every case and the images are of acceptable quality for diagnostic purposes per their laboratory standards. Additional details of the quality control procedures are provided in the device's user manual.

The device interoperable components and computer environment/system requirements are provided in the tables below.

Table 1: WSI scanner

Manufacturer	Model
Hamamatsu	NanoZoomer S360MD Slide scanner
Leica	Aperio GT 450 DX

Table 2: WSI display

Manufacturer	Model
JVC	Kenwood JD-C240BN01A
BARCO	MDPC-8127
Dell	UP3017
Dell	U3023E
Dell	U3223QE

Table 3: Computer environment/System Requirements

Workstation Component	Specifications
Memory	4 GB RAM Capable of supporting at least one of the supported web browsers.
Network connectivity	Internet access Outbound traffic enabled on port 443 25 Mbps download and upload speed
Supported browsers	Google Chrome version 111.0 or later Microsoft Edge version 111.0 or later

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The subject device AISight Dx, is similar to the predicate, in terms of indications for use, intended use and technological characteristics as its predicate devices. The similarities and differences between the AISight Dx and the predicate devices, NanoZoomer S360MD Slide scanner system and Aperio GT 450 DX are summarized in Table 4 below.

Specification	**Predicate Device (K233027)**	**Predicate Device (K232202)**	**Subject Device (K243391)**
Device Trade Name	NanoZoomer S360MD Slide scanner system	Aperio GT 450 DX	AISight Dx
Product Code	PSY	PSY	QKQ
Regulation	21 CFR 864.3700	21 CFR 864.3700	21 CFR 864.3700
Regulation Name	Whole Slide Imaging System	Whole Slide Imaging System	Whole Slide Imaging System (Digital pathology image viewing and management software)
Classification	II	II	II
General Device Characteristics - Similarities			
Indications for Use	The NanoZoomer S360MD Slide scanner system ("NanoZoomer System") is an automated digital slide creation, viewing, and management system. The NanoZoomer 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 NanoZoomer System is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. The NanoZoomer System comprises the NanoZoomer S360MD Slide scanner, the	The Aperio GT 450 DX is an automated digital slide creation and viewing system. The Aperio GT 450 DX 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 Aperio GT 450 DX is for creation and viewing of digital images of scanned glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy. Aperio GT 450 DX is comprised of the Aperio GT 450 DX scanner, which generates images in the Digital Imaging and Communications in Medicine (DICOM) and in the ScanScope Virtual Slide (SVS) file formats, the Aperio WebViewer DX viewer, and the displays. The Aperio GT 450 DX is intended to be used with the interoperable components specified in Table 1. Table 1: Interoperable components of Aperio GT 450 DX	AISight Dx 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 these slides for primary diagnosis. AISight Dx 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. AISight DX is intended to be used

<table>
<tr><th>Specification</th><th>Predicate Device (K233027)</th><th>Predicate Device (K232202)</th><th>Subject Device (K243391)</th></tr>
<tr><td></td><td>NZViewMD Software and a compatible display that has been 510(k) cleared for use with the NanoZoomer system or a 510(k)- cleared display that has been assessed in accordance with the Predetermined Change Control Plan (PCCP) for qualifying additional compatible displays. The NanoZoomer 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 NanoZoomer System.</td><td>
<table>
<tr><th>Scanner Hardware</th><th>Scanner Output file format</th><th>Interoperable Viewing Software</th><th>Interoperable Displays</th></tr>
<tr><td>Aperio GT 450 DX scanner</td><td>SVS</td><td>Aperio WebViewer DX</td><td>Barco MDPC8127 Dell UP3017 Dell U3023E Dell U3223QE</td></tr>
<tr><td>Aperio GT 450 DX scanner</td><td>SVS</td><td>Sectra Digital Pathology Module (3.3)</td><td>Dell U3223QE</td></tr>
<tr><td>Aperio GT 450 DX scanner</td><td>DICOM</td><td>Sectra Digital Pathology Module (3.3)</td><td>Dell U3223QE</td></tr>
</table>

The Aperio GT 450 DX is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. 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 Aperio GT 450 DX.</td><td>with interoperable displays, scanners and file formats, and web browsers that have been 510(k) cleared for use with the AISight Dx or 510(k)-cleared displays, 510(k)-cleared scanners and file formats, and web browsers that have been assessed in accordance with the Predetermined Change Control Plan (PCCP) for qualifying interoperable devices.</td></tr>
<tr><td>Scanner</td><td>Hamamatsu NanoZoomer S360MD Slide scanner</td><td>Aperio Leica GT 450 DX</td><td>Hamamatsu NanoZoomer S360MD Slide scanner, Aperio Leica GT 450 DX, or FDA-cleared scanning hardware validated per the PCCP to ensure performance requirements are met prior to modifications being implemented.</td></tr>
<tr><td>Compatible Display</td><td>JVC Kenwood JD-C24BN01A, BARCO MDPC-8127, or FDA-cleared display validated per the PCCP to ensure performance requirements are met prior to</td><td>BARCO MDPC-8127, Dell UP3017, Dell U3023E, Dell U3223QE</td><td>JVC Kenwood JD-C24BN01A, BARCO MDPC- 8127, Dell UP3017, Dell U3023E, Dell U3223QE, or FDA-cleared display validated per the PCCP to ensure performance requirements are met prior to</td></tr>
</table>

Specification	Predicate Device (K233027)	Predicate Device (K232202)	Subject Device (K243391)
	modifications being implemented.		modifications being implemented.
Specimen Type	Surgical pathology slides prepared from FFPE tissue	Surgical pathology slides prepared from FFPE tissue	Surgical pathology slides prepared from FFPE tissue
Image File Format	NDPI	SVS, DICOM	NDPI, SVS, DICOM
Image Viewing and Measurement Functions	Panning, zooming, image adjustments, annotations, and distance/area measurements	Panning, zooming, gamma function, annotations, and measurements (distance)	Panning, zooming, image adjustments, annotations, and distance/area measurements
General Device Characteristics – Differences			
Type of Software Application	Windows based	Internet browser based	Internet browser based
Device Components	Scanner, Image Management Software and Display	Scanner, Image Management Software and Display	Image Management Software
Principle of Operation	After WSI are acquired by using NanoZoomer S360MD Slide scanner, the WSI are automatically saved to the hard disk during scanning and may be viewed later by using the included viewing software. During review, the pathologist opens WSI from the image storage attached to local network, performs further QC and reads WSI of the slides to make a diagnosis.	The Aperio GT 450 DX is a WSI system. The technician places the slides into the Aperio GT 450 DX scanner. The Aperio GT 450 DX scanner automatically loads the slides, takes the micro images, finds the tissues, and scans the slides. The scanner also automatically performs quality control (QC) and notifies the user of any image quality issue during the image acquisition. The image data is sent to end-user-provided image storage attached to the local network. During the review, the pathologist opens WSI images acquired with the WSI scanner from the image storage, performs further QC, and reads WSI images of the slides to make a diagnosis.	After the WSIs are acquired using the NanoZoomer S360MD Slide scanner or Aperio GT450 DX, the WSIs are stored in customer provided image storage. Images are then ingested into AISight Dx image storage. During image review, the pathologist opens the WSI from AISight Dx image storage; performs further QC and then reads the WSI to make a diagnosis.
User Interface	NZViewMD	Aperio WebViewer DX	AISight Dx

PREDETERMINED CHANGE CONTROL PLAN (PCCP)

This submission provided a PCCP that PathAI will follow to validate compatibility of additional FDA-cleared displays, additional FDA-cleared scanners and file formats and additional web browsers. The PCCP specifies the testing methods, validation activities, and performance requirements to implement those modifications such that the device remains as safe and as effective as the predicate device. With inclusion of the PCCP, future changes to add additional FDA-cleared pathology displays, additional FDA-cleared whole slide imaging scanners and file formats, and additional browsers to the labeling can be made in accordance with the PCCP without a premarket submission. The PathAI website will provide information on additional FDA-cleared WSI components (mentioned above) that are compatible with the AISight Dx and allow users to request updated versions of the system labeling.

PERFORMANCE DATA

Performance data	Description
Pixel-wise Comparison Testing	A pixel-wise comparison test was performed to compare images which were reproduced by AISight Dx for the same image that has been generated by the Leica Aperio GT 450 DX as SVS and DICOM files to validate identical image reproduction. Test results showed that the maximum pixelwise difference between the file formats when displayed in AISight Dx was 0 CIEDE2000, indicating that the output images are pixelwise identical.
Clinical Study	Two separate clinical studies were conducted to support the performance of the AlSight Dx system for reading WSIs compared to the reference method (glass slides read using a traditional light microscope) for the pathology primary diagnosis indication when WSIs are created by Hamamatsu NanoZoomer S360MD (Hamamatsu scanner) or Leica Aperio GT 450 DX scanner (Leica scanner). The clinical studies were conducted to demonstrate that viewing, reviewing, and diagnosing WSIs of H&E stained FFPE tissue slides using AISight Dx [manual digital read (MD)] is non-inferior to glass slide reads using optical (light) microscopy [manual optical (MO)]. The primary endpoint of the study was the difference in major discordance rates between MD and MO when compared to the reference (main) diagnosis, which was the original sign-out pathologic diagnosis using MO [ground truth, (GT)] rendered at the institution. The differences in major discordance rates between MD and GT compared to MO and GT for the Hamamatsu NanoZoomer S360MD Slide scanner were –1.18% (95% CI, -3.49, 1.16) for all cases across the 3 reading pathologists. The differences in major discordance rates between MD and GT compared to MO and GT for the Leica Aperio GT 450

Performance data	Description
	DX were –0.26% (95% CI, -2.71, 2.52) for all cases across the 3 reading pathologists. The upper limit of the CI for the difference in the major discordance rate was 1.16% for the Hamamatsu NanoZoomer S360MD and 2.52% for the Leica Aperio GT 450 DX, which are less than the prespecified noninferiority threshold of 4%, therefore meeting the primary objective of the study.
Turnaround Time Testing	Turnaround times for image processing, image loading, panning, and zooming were tested using Google Chrome and Microsoft Edge using WSIs over a range of sizes. Test results showed these to be adequate for the intended use of the subject device.
Measurements of Area and Distance	Measurement accuracy has been verified by comparing the measurements of markings made in the AISight Dx viewer to the measurements of markings on a NIST calibrated cross scale slide with known sizes. The tests were used to validate the measurement accuracy of the subject device. Tests verified that the distance and area measurements made in the AISight Dx viewer accurately reflected the distance and area of the markings on an image of the calibrated slide. These results show that AISight Dx performed accurate measurements with respect to its intended use.
Human Factors Validation Study	AISight Dx has been found to be safe and effective for the intended users, uses, and use environments.

CONCLUSION

Based on the information provided in the 510(k), the subject device AISight Dx is substantially equivalent to the previously cleared predicate device, when used with the Hamamatsu NanoZoomer S360MD Slide scanner or Leica Aperio GT 450 DX and JVC Kenwood JD-C24BN01A, BARCO MDPC-8127, Dell UP3017, Dell U3023E, and Dell U3223QE monitors. Clinical studies were conducted to establish the Substantial Equivalence of the device.