PathPresenter Corporation
Brian Matcheski
Regulatory Manager
19 Louis Drive
Montville, NJ 07045

June 20, 2025

Re: K250968
Trade/Device Name: PathPresenter Clinical Viewer
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: QKQ
Dated: March 17, 2025
Received: March 31, 2025

Dear Brian Matcheski:

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.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250968

Device Name
PathPresenter Clinical Viewer

Indications for Use *(Describe)*

For In Vitro Diagnostic Use

The PathPresenter Clinical Viewer is a software intended for viewing and managing whole slide images of scanned glass sides derived from formalin fixed paraffin embedded (FFPE) tissue. It is an aid to pathologists to review and render a diagnosis using the digital images for the purposes of primary diagnosis. PathPresenter Clinical is not intended for use with frozen sections, cytology specimens, or non-FFPE specimens. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using PathPresenter Clinical software. PathPresenter Clinical Viewer is intended for use with Hamamatsu NanoZoomer S360MD Slide scanner NDPI image formats viewed on the Barco NV MDPC-8127 display device.

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
PathPresenter Clinical Viewer

Date Prepared: June 20, 2025

Submitter

PathPresenter Corporation
19 Louis Drive Montville NJ 07045

Contact Person

Brian Matcheski
Regulatory Manager
19 Louis Drive Montville NJ 07045
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Device

Device Trade Name:	PathPresenter Clinical
Viewer Version:	V1.0.1
Classification Name:	Whole Slide Imaging System
Regulation Number:	21 CFR 864.3700
Product Code(s):	QKQ
Device Class:	Class II
Review Panel	88-Pathology
Common Name:	PathPresenter Clinical Viewer
510(k) Number:	K250968

Predicate Devices

Trade Name:	NanoZoomer S360MD Slide scanner system
Submission Number:	K233027
Device Class:	Class II
CFR Section:	864.3700
Product Code:	PSY
Classification Name:	Whole Slide Imaging System

INDICATIONS FOR USE

For In Vitro Diagnostic Use

The PathPresenter Clinical Viewer is a software intended for viewing and managing whole slide images of scanned glass sides derived from formalin fixed paraffin embedded (FFPE) tissue. It is an aid to pathologists to review and render a diagnosis using the digital images for the purposes of primary diagnosis. PathPresenter Clinical is not intended for use with frozen sections, cytology specimens, or non-FFPE specimens. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using PathPresenter Clinical software. PathPresenter Clinical Viewer is intended for use with Hamamatsu NanoZoomer S360MD Slide scanner NDPI image formats viewed on the Barco NV MDPC-8127 display device.

Device Description

The PathPresenter Clinical Viewer (version V1.0.1) is a web-based software application designed for viewing and managing whole slide images generated from scanned glass slides of formalin-fixed, paraffin- embedded (FFPE) surgical pathology tissue. It serves as a diagnostic aid, enabling pathologists to review digital images and render a primary pathology diagnosis. Functions of the viewer include zooming and panning the image, annotating the image, measuring distances and areas in the image and retrieving multiple images from the slide tray including prior cases and deprecated slides.

The PathPresenter Clinical Viewer is validated for use with the FDA cleared components specified below in Table 1.

Table 1: Interoperable Components

Scanner Hardware	Scanner Output File	Interoperable Displays
Hamamatsu NanoZoomer S360MD Slide Scanner	NDPI	Barco NV MDPC-8127

Table 2: System Requirements

Environment	Component	Minimum Requirements
Hardware	Processor	CPU: quad core CPU >2GHZ
	Memory	8GB RAM
	Network	100 Mbps connection (1Gbps LAN recommended)
	Monitor	Full HD (1920 x 1080 pixels
Software	Operating System	Windows 10 (64-bit); Mac OS

	Browser	Google Chrome v114.0.5735.199 or higher Microsoft Edge v114.0.1823.67 or higher

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Item	Subject Device (K250968)	Predicate Device (K233027)
Device Trade Name	PathPresenter Clinical Viewer	NanoZoomer S360MD Slide scanner system
General Device Characteristics - Similarities		
Intended Use / Indications for Use	For In Vitro Diagnostic Use The PathPresenter Clinical Viewer is a software intended for viewing and managing whole slide images of scanned glass sides derived from formalin fixed paraffin embedded (FFPE) tissue. It is an aid to pathologists to review and render a diagnosis using the digital images for the purposes of primary diagnosis. PathPresenter Clinical is not intended for use with frozen sections, cytology specimens, or non-FFPE specimens. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using PathPresenter Clinical software. PathPresenter Clinical Viewer is intended for use with Hamamatsu NanoZoomer S360MD Slide scanner NDPI image formats viewed on the Barco NV MDPC-8127 display device.	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 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

Item	Subject Device (K250968)	Predicate Device (K233027)
		procedures and safeguards to assure the validity of the interpretation of images obtained using the NanoZoomer System.
Specimen Type	Same	Surgical pathology slides prepared from FFPE tissue
Diagnostic Image File Format	Same	Hamamatsu NDPI File
Image Storage	Same	User-supplied network attached storage
Image Manipulation Functions	Same	Panning, Zooming, Image Adjustments, applying annotation and distance / area measurements
General Device Characteristics - Differences		
Principle of Operation	A digital pathology image management and analysis platform designed for clinical diagnostics. It operates by receiving whole slide NDPI images from the Hamamatsu NanoZoomer S360MD	Hamamatsu NZViewMD is a digital pathology viewing software designed for clinical diagnostics. It operates by receiving whole slide NDPI images scanned by the Hamamatsu NanoZoomer S360MD and enables users to view, navigate, and review these images on a computer display. NZViewMD simulates traditional microscope interaction by providing digital zoom, pan, and slide navigation tools, supporting clinical assessment of digitized pathology slides.
Type of SW Application	Internet Browser Based	Desktop
Viewer	PathPresenter Clinical Viewer	NZViewMD

Summary of Performance Data

Test	Result
Pixelwise Comparison:	The subject device (PathPresenter Clinical Viewer on both Microsoft Edge and Google Chrome browsers) demonstrates substantial equivalence of the pixelwise comparison with the predicate device (Hamamatsu NZViewMD). The image review manipulation software (IRMS) of the PathPresenter Clinical Viewer (Subject Viewer) generates equivalent images, with respect to color, as the Hamamatsu NanoZoomer S360MD Slide scanner with NZViewMD viewer (Predicate Viewer) for the same input files. The IRMS of the PathPresenter Clinical Viewer was accepted as equivalent to the Hamamatsu NanoZoomer NZViewMD viewer since the 95th percentile of the pixel-wise color difference in any image pair is less than 3 CIEDE2000 (< 3 ΔE00). The sample set was composed from images from 30 FFPE tissue glass slides from 15 different anatomical locations. For each slide, three (3) Regions of Interest (ROIs) were selected by a board-certified Pathologist. The pathologist, blinded to the rest of the pixel- wise comparison study, pre- identified the regions of interest as a service to the Development Team. This ensured that each ROI included relevant biological features while minimizing blank areas. From each ROI, two (2) zoom levels, specifically 20x and 40x are used to capture the images. Total Image Pairs: 30 slides x 3 ROIs x 3 Zoom Levels x 2 Browsers = 180. The PathPresenter Clinical Viewer is intended to be used with Microsoft Edge and Google Chrome Internet web browsers. Test images were analyzed across each device-browser combination, specifically comparing the PathPresenter Clinical View launched in Chrome with the Hamamatsu NZViewMD, and the PathPresenter Clinical View launched in Edge with the Hamamatsu NZViewMD.
Turnaround Time Study	TAT bench studies evaluated the average time required to execute zooming and panning operations, and to refresh the display in response to user input. Using a minimum of 20 slides, the evaluation concluded that for different scenarios, the PathPresenter Clinical Viewer met the test acceptance criteria and showed acceptable turnaround time for the intended use of the subject device. Average times required to execute opening, zooming and panning operations, and to refresh the display in response to user input meets established targets.: • Loading of the first image visible to the user; Target: 8 seconds, Actual: 2.72 seconds • Loading of the whole field of view after panning; Target: 2 seconds, Actual 1.22 seconds • Loading of the whole field of view after zooming; Target: 3 seconds, Actual: 0.60seconds

Measurement Accuracy	The measurement accuracy of the PathPresenter Annotation tools were evaluated for both length and area across multiple magnification levels. To verify its accuracy, an image of a calibration scale slide with objects of known sizes was used. A series of annotations were created at various magnifications in two intended browsers. The differences between actual and reported measurements were calculated for each annotation. The acceptance criteria required that all measured values match predetermined measurements relevant to the zoom level of the viewer, with no allowable deviation. Test results demonstrated that the PathPresenter Annotation tools performed highly accurate measurements of both length and area. All measured values matched the reference values exactly, with zero observed error across multiple magnification settings, confirming the tool's precision for its intended use.
Human Factors Study	Human Factors (HF) validation test was conducted to demonstrate that the PathPresenter Clinical Viewer can be used by pathologists, free from serious use errors or problems under the expected use conditions. A systematic evaluation of task-based usability including critical tasks required for operation of the device were evaluated via a Use-Related Risk Analysis (URRA). The HF validation test was performed by representative users (board-certified pathologists) and conducted per FDA's Guidance on Applying Human Factors and Usability Engineering to Medical Devices (2016). Validation results confirmed that critical tasks were performed accurately and without any use-related errors that could result in patient harm or diagnostic inaccuracies. Observed usability issues are easily mitigated through minor design improvements, addressed via training and labeling, and determined to pose no unacceptable risk to user performance or patient safety. Based on these findings, the PathPresenter Clinical Viewer meets HFE/UE requirements and is acceptable for deployment use in clinical settings.

CONCLUSION

Based on the required nonclinical testing the PathPresenter Clinical Viewer meets are the Technical Performance Requirements and supports a substantial equivalence claim to the predicate device.