510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K250968

B Applicant

PathPresenter Corporation

C Proprietary and Established Names

PathPresenter Clinical Viewer

D Regulatory Information

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

II Submission/Device Overview:

A Purpose for Submission:

New device

B Type of Test:

Digital pathology software only device

III Intended Use/Indications for Use:

A Intended Use(s):

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.

B Indication(s) for Use:

Same as Intended Use.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The PathPresenter Clinical Viewer (version V1.0.1) is a web-based software application designed for viewing and managing whole slide images (WSIs) 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 operated as follows: Image acquisition is performed using the intended scanner, with the operator conducting quality control on the whole-slide images according to the scanner's instructions for use and local laboratory procedures to determine if re-scans are needed. The WSIs are then sent to an end-user-provided image storage. Pathologists access the digital image through PathPresenter Clinical Viewer from a worklist. They use various tools to view, annotate and analyze the images, using features like zoom, pan, and measurement. Pathologists review and interpret the digital images to render a diagnosis.

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

Table 1: Interoperable Components

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

Table 2: Computer Environment/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

B Instrument Description Information:

1. Instrument Name:
   PathPresenter Clinical Viewer

2. Specimen Identification:
   Glass slides and scanned images are identified based on the previously assigned specimen identifiers such as patient identifiers, barcodes, etc. Digital images of Hematoxylin and Eosin (H&E) stained surgical pathology glass slides prepared from FFPE tissue are obtained using the Hamamatsu NanoZoomer S360MD Slide scanner. A reading pathologist selects a case (patient) from an external worklist, and the subject device retrieves the corresponding images from external image storage. The scanned images are identified using the specimen identifier previously assigned to the case.

3. Specimen Sampling and Handling:
   Specimen sampling and handling are performed upstream and independent of the use of the subject device. Specimen sampling includes surgical pathology specimens such as biopsy or resection specimens which are processed using standard histology techniques. The FFPE tissue sections are stained using the Hematoxylin and Eosin (H&E) staining procedure. Then digital images are obtained from these glass slides using the Hamamatsu S360MD Slide scanner.

4. Calibration:
   Not Applicable

5. 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.

V Substantial Equivalence Information:

A Predicate Device Name(s):

NanoZoomer S360MD Slide scanner system.

B Predicate 510(k) Number(s):

K233027

C Comparison with Predicate(s):

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	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

Item	Subject Device (K250968)	Predicate Device (K233027)
	Barco NV MDPC-8127 display device.	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 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

VI Standards/Guidance Documents Referenced:

1. Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices: Guidance for Industry and Food and Drug Administration Staff, April 20, 2016.
2. Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff February 3, 2016.

3. Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff September 27, 2023.
4. IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software – Software life cycle processes (recognition Number 13-79).
5. ISO 14971 Third Edition 2019-12, Medical devices – Applications of risk management to medical devices (recognition Number 5-125).
6. IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Application of usability engineering to medical devices (recognition Number 5-129).

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. Assay Reportable Range:
   Not applicable

5. Accuracy (Instrument):
   Not applicable

6. Carry-Over:
   Not applicable

B Other Supportive Instrument Performance Characteristics Data:

1. Bench Testing – Pixelwise comparison test

Pixel-wise comparison testing to demonstrate identical image reproduction was conducted to compare WSIs reproduced by the subject device and the comparator as listed in Table 3 below. The subject device was compared to the predicate device's image review manipulation software (IRMS, as defined in FDA guidance document, "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices" dated April 20, 2016) using the quantitative pixel-wise comparison method. The basis for the comparison was the CIEDE2000 color difference equation, ΔE00. The devices were tested as operating with the intended components, including the scanner, specific file format, image management systems [subject device with the intended browsers (Microsoft Edge and Google Chrome), comparator (predicate device IRMS)] and display, as specified in the Table 3 below.

A total of 30 FFPE tissue slides from 15 different anatomical locations such as breast,

prostate, gastrointestinal tract, lung, lymph node, bone, etc. were used in the study. The 30 glass slides were scanned with a Hamamatsu NanoZoomer S360MD scanner to generate WSI files in the NDPI file format. For each of the 30 slides, 3 regions of interests (ROIs) were manually selected by a board-certified pathologist to represent various features in the tissue samples. The pathologist, blinded to the rest of the pixel- wise comparison study, pre-identified the regions of interest. This ensured that each ROI included relevant biological features while minimizing blank areas. Blank or blurry areas were excluded from the ROI selection. The ROIs were captured at 20x and 40x magnification levels.

For each configuration, 180 image-pairs (30 slides * 3 ROIs * 2 magnification levels) were tested for a total of 360 image pairs (30 slides x 3 ROIs x 2 Zoom Levels x 2 Browsers = 360). For each comparison, screenshots were captured from the subject with NDPI image file format to be opened via subject viewer and the predicate, to form an image-pair. Each image-pair was cropped and registered to be pixelwise comparable. The cropped image included most of the pixels in the image except for those in the viewer-specific user interface areas. The testing data, including the screenshots and cropping/registration information of the testing configurations were provided in the FDA specific format.

For each image-pair, the pixelwise differences between two images were calculated using the CIEDE2000 color difference metric. Two images were considered to be identical if the 95th percentile of the pixelwise color differences is less than 3 CIEDE2000 (< 3 ΔE00). Based on analysis of the testing data, WSIs reproduced by PathPresenter Clinical Viewer and the predicate were identical, i.e., < 3 ΔE00.

Table 3: Pixelwise Comparison Testing Results

Scanner/ Image File Format	**Subject Device/ Browser**	**Comparator (Predicate device IRMS/ Browser)**	**Display**	**Results**
Hamamatsu NanoZoomer S360MD Slide Scanner/ NDPI	PathPresenter Clinical Viewer/ Edge	NZViewMD/ Edge	Barco NV MDPC-8127	max (95th percentile ΔE00) = 2.98 min (95th percentile ΔE00) = 1.39 mean (95th percentile ΔE00) = 2.17
	PathPresenter Clinical Viewer/ Chrome	NZViewMD/ Chrome		max (95th percentile ΔE00) = 2.99 min (95th percentile ΔE00) = 1.39 mean (95th percentile ΔE00) =2.17

2. Turnaround Time (TAT)

The purpose of this test was to demonstrate that the turnaround time for rendering of images is acceptable. TAT bench studies evaluated the average time required to execute zooming and panning operations, and to refresh the display in response to user input. A minimum of 20 slides were used in this study which evaluated various image manipulation scenarios including opening, zooming (at 5x, 10x, and 40x), and panning (vertically and horizontally) operations. The sponsor tested these scenarios using both Google Chrome and Microsoft Edge browsers, ensuring consistent performance across platforms. 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: 0.60 seconds.

3. Measurements (area and distance)

The purpose of this test was to demonstrate that PathPresenter Clinical Viewer accurately shows measurement annotations on scanned WSIs from the Hamamatsu S360 scanner. The measurement accuracy of the PathPresenter Annotation feature was 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 feature performed accurate measurements of both length and area. All measured values matched the reference values exactly, with zero observed error across multiple magnification settings.

4. Human factor (Usability) Testing

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.

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.