510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K251952

B Applicant

Virasoft Corporation

C Proprietary and Established Names

ViraSight

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:

Software only device

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

ViraSight is a web-based software-only device intended to aid pathologists in the viewing and management of digital images of scanned pathology slides prepared from formalin-fixed, paraffin-

embedded (FFPE) tissue. It is an aid to the pathologist to review these digital images for the purposes of pathology primary diagnosis.

ViraSight 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 ViraSight.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

ViraSight (version 1.0.6), is a web-based, software-only device intended to aid pathologists in the viewing and management of digital images of scanned pathology slides prepared from formalin-fixed, paraffin-embedded (FFPE) tissue acquired from FDA-cleared digital pathology scanners on FDA-cleared displays, as specified in Tables 1 and 2 below. ViraSight is an image viewing software and does not include image analysis or perform diagnostic functions.

Glass slide scanning is performed upstream and independent of the use of ViraSight. Image acquisition is performed using the intended scanner(s), the Hamamatsu NanoZoomer S360MD Slide Scanner or the Leica Aperio GT 450 DX Scanner; with the scanning technician conducting quality control on the whole-slide images according to the scanner's instructions for use and laboratory specifications to determine if re-scans are needed.

The primary tasks within the ViraSight workflow completed by the user in the user interface are:

1. Logging into ViraSight
2. Loading and opening a digital slide
3. Navigating (including panning and zooming) the slide
4. Rotating the slide
5. Measuring distances and area in the digital image
6. Annotating regions of interest
7. Referring annotations to notes
8. Entering, finalizing and saving the pathologist’s diagnosis as a note
9. Completing case review and logout

ViraSight is validated for use with the WSI scanner specified in Tables 1, display components specified in Table 2, and computer environment specified in Table 3.

Table 1: WSI scanner

Manufacturer	Device name
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 Requirements

Workstation Component	Specifications
Memory	Minimum 16 GB
CPU	Minimum 4 cores
Network Bandwidth	50 Mbps bandwidth to the server
Operating System	Microsoft Windows 11
Supported browsers	Google Chrome (146.0.7680.178 and above) Microsoft Edge (146.0.3856.97 and above)

B Instrument Description Information:

1. Instrument Name:
   ViraSight

2. Specimen Identification:
   The ViraSight device utilizes digital pathology images acquired from Hematoxylin and Eosin (H&E) stained glass slides using the Hamamatsu NanoZoomer S360MD Slide scanner or the Leica Aperio GT 450 DX scanner. A reading pathologist selects a case (patient) from an external worklist, and the subject device retrieves the corresponding images acquired by the WSI scanner. The scanned images are identified using the specimen identifier previously assigned to the case.

3. Specimen Sampling and Handling:
   Specimen sampling and handling are conducted independently and prior to the use of the subject device. This process involves obtaining biopsy or resection specimens, which are then processed using standard histology techniques. After H&E staining of the FFPE tissue sections, digital images are generated from the glass slides using the Hamamatsu NanoZoomer S360MD Slide scanner or the Leica Aperio GT 450 DX Scanner.

4. Calibration:
   Not applicable

5. Quality Control:

   Quality control procedures should be established by the laboratory in accordance with its standard operating procedures. Before using ViraSight for primary diagnosis, the user should verify that the

correct case has been selected and that all associated whole slide images have been successfully imported and are complete and of acceptable image quality for diagnostic review. Image quality should be assessed for factors such as focus, completeness of the scanned tissue, and the presence of artifacts that may interfere with interpretation. If image quality is considered inadequate for diagnostic purposes, the slide should be rescanned or reviewed using the laboratory's established procedures. ViraSight does not perform automated quality assessment of whole slide images and does not determine whether an image is acceptable for diagnosis. The final determination of image quality and suitability for diagnostic use remains the responsibility of the reviewing pathologist and the laboratory.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Aperio GT 450 DX; NanoZoomer S360MD Slide scanner system

B Predicate 510(k) Number(s):
K232202, K213883

C Comparison with Predicate(s):

Specification	Subject Device (K251952)	Predicate Device (K232202)	Predicate Device (K213883)
Device Trade Name	ViraSight	Aperio GT 450 DX	NanoZoomer S360MD Slide scanner system
Product Code	QKQ	PSY	PSY
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
Classification	II	II	II
General Device Characteristic Similarities			
Indications for Use	ViraSight is a web-based software-only device intended to aid pathologists in the viewing and management of digital images of scanned pathology slides prepared from formalin-fixed, paraffin-embedded (FFPE) tissue. It is an aid to the pathologist to review these digital images for the purposes of pathology primary diagnosis. ViraSight is not intended for use with frozen section, cytology, or non-FFPE hematopathology	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.	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.

<table>
<tr><th>Specification</th><th>Subject Device (K251952)</th><th>Predicate Device (K232202)</th><th>Predicate Device (K213883)</th></tr>
<tr><td></td><td>specimens. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using ViraSight.</td><td>Table 1: Interoperable components of Aperio GT 450 DX
<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 MDPC-8127
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>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 procedures and safeguards to assure the validity of the interpretation of images obtained using NanoZoomer System</td></tr>
<tr><td>Scanner</td><td>Hamamatsu NanoZoomer S360MD Slide scanner and Leica Aperio GT 450 DX</td><td>Leica Aperio GT 450 DX</td><td>Hamamatsu NanoZoomer S360MD Slide scanner</td></tr>
<tr><td>Interoperable Display</td><td>JVC Kenwood JD-C240BN01A
Dell U3223QE
Dell UP3017 Dell U3023E
Barco MDPC-8127</td><td>Barco MDPC-8127, Dell UP3017, Dell U3023E, Dell U3223QE</td><td>JVC Kenwood JD-C240BN01A, Barco MDPC-8127</td></tr>
<tr><td>Specimen Type</td><td>Surgical pathology slides prepared from FFPE tissue</td><td>Same</td><td>Same</td></tr>
<tr><td>Image File Format</td><td>SVS, NDPI</td><td>SVS, DICOM</td><td>NDPI</td></tr>
<tr><td>Image Manipulation Functions</td><td>Panning, zooming, image adjustments, annotations, and distance/area measurements</td><td>Panning, zooming, gamma function, annotations, and measurements</td><td>Panning, zooming, image adjustments, annotations, and distance/area measurements</td></tr>
<tr><td>Principle of Operation</td><td>ViraSight is a web-based, software-only device intended to aid pathologists in the viewing and management of digital images of scanned pathology slides prepared from</td><td>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</td><td>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.</td></tr>
</table>

Specification	Subject Device (K251952)	Predicate Device (K232202)	Predicate Device (K213883)
	formalin-fixed, paraffin-embedded (FFPE) tissue from Hamamatsu NanoZoomer S360MD Slide scanner or Leica Aperio GT 450 DX scanner. Glass slide scanning is performed upstream and independent of the use of ViraSight. The scanning technician should perform quality control of all glass slides and WSIs following the scanner Instructions for Use and other laboratory procedures. Prior to using a WSI for diagnosis, the pathologist should ensure that all scanned slide images have been imported for every case and the images are of acceptable quality for diagnostic purposes. The pathologist reviews scanned images from all the slides associated with a case before rendering a diagnosis. ViraSight supports navigation and visualization of whole-slide images, annotation and measurement of regions of interest, creation of notes referring to annotations, color adjustment of image to edit brightness and contrast.	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.	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.
Device Components	ViraSight Image Management System and Monitor display	Scanner, Image Management Software, and Display	Scanner, Image Management Software, and Display
General Device Characteristic Differences			
User Interface	ViraSight	Aperio WebViewer DX	NZViewMD

VI Standards/Guidance Documents Referenced:

1. FDA Guidance “Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices". April 20, 2016.
2. FDA Guidance “Applying Human Factors and Usability Engineering to Medical Devices”. February 3,

2016.
3. FDA Guidance "Content of Premarket Submissions for Device Software Functions". June 14, 2023.
4. FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". September 27, 2023.
5. IEC 62304:2006 + A1:2015 – Medical Device Software – Software Life Cycle Processes
6. ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
7. ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices
8. IEC 62366-1:2015 + A1:2020 – Application of Usability Engineering to Medical Devices

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 was conducted with the subject device, ViraSight as specified below.

1. Bench Testing - Pixelwise comparison test

Pixel-wise comparison testing was conducted to compare images reproduced by ViraSight and the comparators; the predicate device's Image Review Manipulation Software (IRMS, as defined in the FDA guidance document Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices, dated April 20, 2016) — as described below for the same whole slide image generated from an interoperable scanner, to validate equivalent image reproduction. The equivalence between ViraSight and the comparators was evaluated by bench testing based on pixel-wise comparison for both supported scanner file formats: SVS files generated by the Leica Aperio GT 450 DX scanner, and NDPI files generated by the Hamamatsu NanoZoomer S360MD scanner.

Pixelwise comparison testing was performed with the assistance of the "Image Viewer Integrity Evaluation System (IVIES)" application, which is an FDA-qualified Medical Device Development Tool [MDDT; Image Viewer Integrity Evaluation System (IVIES)]. ViraSight was tested as operating with its intended components, including the scanner and monitor display, to evaluate the pixel-wise differences. A total of 48 formalin-fixed, paraffin-embedded (FFPE) pathology tissue glass slides,

covering a range of tissue types and diagnostic categories, were scanned using both slide scanner systems. For each WSI dataset, three rectangular regions of interest (ROIs) were identified per slide. Screenshots of these ROIs were captured at two magnification levels, 20x and 40x, on the Dell U3023E display. For SVS files, ViraSight screenshots were compared against Leica Aperio WebViewer DX screenshots under matched browser conditions in Google Chrome and Microsoft Edge. For NDPI files, screenshots of ViraSight running in Google Chrome and Microsoft Edge were compared against Hamamatsu NZViewMD screenshots. The original 640×480 ROI screenshots were cropped to 630×470 pixels to remove annotation boundary visuals, and every pixel of each cropped screenshot pair was sampled to calculate the pixel-wise color difference using the CIEDE2000 (ΔE_{00}) metric through IVIES. The acceptance criterion required that the 95th percentile of the pixel-wise color differences in every ROI image pair between ViraSight and the comparator must be less than 3 CIEDE2000 (i.e., $< 3\ \Delta E_{00}$).

The test results demonstrated that the maximum 95th percentile of pixel-wise color differences between ViraSight and any comparator was less than 3 CIEDE2000 across all comparison sets (e.g., all scanners, file formats, browsers, and magnification levels). No tested ROI image pair exceeded the $\Delta E_{00} = 3$ threshold at the 95th percentile, indicating that ViraSight output images were visually consistent with the comparators for both supported scanner file formats across all tested browser conditions and viewer zoom levels. The detailed pixel-wise comparison test results, including the maximum, minimum, and mean 95th percentile ΔE_{00} values across all ROI pairs for each scanner, file format, subject device/browser, comparator, and magnification level, are provided in the Table 4 below.

Therefore, testing results demonstrated that WSIs reproduced by ViraSight are identical to images reproduced by the predicate devices.

Table 4. ViraSight Pixelwise Comparison Testing Results

Scanner	Image File Format	Subject Device/ Browser	Comparator (Predicate device IRMS /Browser)	Magnification Level	Results
Hamamatsu NanoZoomer S360MD Scanner	NDPI	ViraSight / Chrome	Hamamatsu NZViewMD	40x	max (95th percentile ΔE00) = 0.69 min (95th percentile ΔE00) = 0.36 mean (95th percentile ΔE00) = 0.47
				20x	max (95th percentile ΔE00) = 1.61 min (95th percentile ΔE00) = 0.37 mean (95th percentile ΔE00) = 0.68
		ViraSight / Edge		40x	max (95th percentile ΔE00) = 0.69 min (95th percentile ΔE00) = 0.36 mean (95th percentile ΔE00) = 0.47
				20x	max (95th percentile ΔE00) = 1.60 min (95th percentile ΔE00) = 0.37 mean (95th percentile ΔE00) = 0.67
Leica Aperio GT 450 DX Scanner	SVS	ViraSight / Chrome	Leica Aperio WebViewer DX / Chrome	40x	max (95th percentile ΔE00) = 2.96 min (95th percentile ΔE00) = 0.94 mean (95th percentile ΔE00) = 2.08
				20x	max (95th percentile ΔE00) = 2.93 min (95th percentile ΔE00) = 1.23 mean (95th percentile ΔE00) = 2.27

		ViraSight /Edge	Leica Aperio WebViewer DX /Edge	40x	max (95th percentile ΔE00) = 2.98 min (95th percentile ΔE00) = 0.95 mean (95th percentile ΔE00) = 2.11
				20x	max (95th percentile ΔE00) = 2.93 min (95th percentile ΔE00) = 1.23 mean (95th percentile ΔE00) = 2.27

2. Turnaround Time Testing

Turnaround time (TAT) testing was performed to demonstrate that ViraSight provides acceptable image rendering performance for the intended use of the subject device. A total of 30 H&E-stained FFPE tissue glass slides were scanned using the intended scanners to generate 30 WSIs in SVS format and 30 WSIs in NDPI format. TAT testing was performed across all supported browsers — Google Chrome and Microsoft Edge — and both supported scanner file formats. Each browser/file-format configuration was tested in two independent runs using WSIs over a range of file sizes.

Turnaround time values were recorded for WSI loading, 20X zooming, 40X zooming, and panning. All tested WSIs were loaded successfully, and zooming and panning operations were completed without rendering failure, application crash, loss of image data or interruption preventing intended use.

The test results demonstrated acceptable turnaround time performance across all tested browser environments and supported file formats with respect to the intended use of the subject device, as shown in Table 5 below.

Table 5. ViraSight Turnaround Time Testing Results

Scanner	**Image File Format**	**Subject Device / Browser**	**Results (Sec)**			
			Loading	**20X Zooming**	**40X Zooming**	**Panning**
Leica Aperio GT 450 DX scanner	SVS	ViraSight / Chrome	Mean = 1.032 Range = 0.594–1.717	Mean = 1.655 Range = 0.553–3.343	Mean = 0.403 Range = 0.014–3.595	Mean = 0.172 Range = 0.062–0.504
		ViraSight / Edge	Mean = 0.952 Range = 0.653–1.839	Mean = 1.084 Range = 0.081–2.304	Mean = 0.192 Range = 0.057–2.018	Mean = 0.104 Range = 0.020–0.363
Hamamatsu NanoZoomer S360MD Slide scanner	NDPI	ViraSight / Chrome	Mean = 0.833 Range = 0.664–1.178	Mean = 1.970 Range = 0.845–3.137	Mean = 0.224 Range = 0.076–0.942	Mean = 0.116 Range = 0.062–0.286
		ViraSight / Edge	Mean = 0.869 Range = 0.675–1.407	Mean = 1.727 Range = 0.409–2.960	Mean = 0.248 Range = 0.058–0.807	Mean = 0.145 Range = 0.075–1.345

Therefore, ViraSight has been found to have acceptable turnaround time performance with respect to its intended use.

3. **Measurement – distance and area**

Measurement accuracy testing was conducted to demonstrate that ViraSight accurately represents length and area measurements across the supported scanner file formats, intended browser environments, viewer magnification levels, and slide orientations. A total of three H&E-stained FFPE tissue slides, and one calibration/reference slide were used as the test input. The slides were represented in SVS and NDPI formats using the intended scanners. All supported browsers — Google Chrome and Microsoft Edge — two viewer magnification levels (20x and 40x), horizontal and vertical slide orientations, and two types of measurements — length and area — were tested. Area measurements included rectangle/square, circle/ellipse, and freehand region measurements where supported.

Measurement accuracy was evaluated by comparing the ViraSight-generated measurement values against the applicable reference values, which were based on known reference dimensions, reference screenshots, or measurements from the applicable reference viewer where technically supported. The acceptance criterion required less than 0.01% difference between the ViraSight-generated measurement and the applicable reference value.

The test results demonstrated that the pre-specified acceptance criterion of < 0.01% difference was met across all tested configurations. All completed measurement records were exact matches with no error, as listed in Table 6 below.

Table 6. ViraSight Measurement Results

Scanner	Image Format	Subject Device / Browser	Percent Difference (%)	
			Length Measurement	Area Measurement
Leica Aperio GT 450 DX scanner	SVS	ViraSight / Chrome	0	0
		ViraSight / Edge	0	0
Hamamatsu NanoZoomer S360MD Slide scanner	NDPI	ViraSight / Chrome	0	0
		ViraSight / Edge	0	0

Therefore, ViraSight has been found to perform accurate length and area measurements with respect to its intended use.

4. **Human Factor (Usability) Testing**

Human factors validation testing was conducted per FDA guidance Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016), using task-based use scenarios performed by representative users across two sites under simulated use conditions representative of the intended

clinical environment. A systematic evaluation of critical tasks required for the intended operation of ViraSight was performed by 15 representative users, including pathologists as primary users and laboratory technicians as secondary users. 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.