July 17, 2026

Virasoft Corporation
Ted Baird
Chief Commercial Officer
104 W 49th St.
Suites 400 and 500
New York City, NY 10018

Re: K251952
Trade/Device Name: Virasight
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Class: Class II
Product Code: QKQ
Dated: May 26, 2025
Received: June 25, 2025

Dear Ted Baird:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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)*
K251952

Device Name
ViraSight

Indications for Use *(Describe)*
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.

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.

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510(k) Summary
ViraSight

DATE PREPARED: July 16, 2026

SUBMITTER/510(k) HOLDER
Company Name: Virasoft Corporation
Address 1: 104 W 49th St. Suites 400 And 500
New York City, NY 10018 UNITED STATES

Primary Contact Person Name: Ted Regan Baird
Title: Chief Commercial Officer
Telephone: +1 (857) 928-5099

DEVICE

Proprietary Name:	ViraSight
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

PREDICATE DEVICES

Proprietary Name:	NanoZoomer S360MD Slide scanner system
Submission Number:	K213883

Proprietary Name:	Aperio GT 450 DX
Submission Number:	K232202

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 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.

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 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.

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

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 the slide
4. Rotating the slide
5. Measuring distances in the digital image
6. Annotating regions of interest
7. Referring annotations to notes
8. Finalizing and saving the diagnosis as a note.
9. Completing case review and logout

ViraSight must operate with and is validated for use with specified components as defined in Tables 1 and 2, and system requirements, as defined 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: System 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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The subject device is similar to each predicate, having similar indications for use, intended use and technological characteristics as its predicate device, and is therefore substantially equivalent to each predicate device.

	Subject Device ViraSight (K251952)	**Primary Predicate** Aperio GT 450 DX (K232202)	**Secondary Predicate** NanoZoomer S360MD Slide scanner system (K213883)
Regulation Number	21 CFR 864.3700	21 CFR 864.3700	21 CFR 864.3700
Classification Name	whole slide imaging system	whole slide imaging system	whole slide imaging system
Product Code	QKQ	PSY	PSY
Device Class	Class II	Class II	Class II
OTC or Rx	Rx - For Prescription Use Only	Rx - For Prescription Use Only For In vitro diagnostic (IVD) use only	Rx - For Prescription Use Only For In vitro diagnostic (IVD) use only
Indication 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	The Aperio GT 450 DX is an automated digital slide creation and viewing system. The Aperio GT450 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	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

<table>
<tr><th></th><th>Subject Device
ViraSight
(K251952)</th><th>Primary Predicate
Aperio GT 450 DX
(K232202)</th><th>Secondary Predicate
NanoZoomer S360MD Slide scanner system
(K213883)</th></tr>
<tr><td></td><td>of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using ViraSight. ViraSight</td><td>viewer, and the displays. The Aperio GT450 DX is intended to be used with the interoperable components specified in Table 1.

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>with frozen section, cytology, or non-FFPE hematopathology specimens. The NanoZoomer System comprises the NanoZoomer S360MD Slide scanner, the NZViewMD Software and the JVC Kenwood JD-C240BN01A display. 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>Device Components</td><td>ViraSight Image Management System Monitor display</td><td>WSI scanner (Aperio GT450 DX scanner), Image Management System (Aperio WebViewer DX image viewing software) and color monitor display</td><td>NanoZoomer S360MD Slide scanner which includes the NZAcquireMD image acquisition software 1.0.0
NZViewMD Software 1.0.0
Monitor display</td></tr>
<tr><td>Interoperable Display (Monitor)</td><td>JVC Kenwood JD-C240BN01A
Dell U3223QE
Dell UP3017
Dell U3023E
Barco MDPC-8127</td><td>DELL UP3017
Dell U3023E
Dell U3223QE
Barco MDPC-8127</td><td>JVC Kenwood JD-C240BN01A</td></tr>
<tr><td>Specimen Type</td><td>Surgical pathology slides prepared from FFPE tissue</td><td>Surgical pathology slides prepared from FFPE tissue</td><td>Surgical pathology slides prepared from FFPE tissue</td></tr>
</table>

	Subject Device ViraSight (K251952)	**Primary Predicate** Aperio GT 450 DX (K232202)	**Secondary Predicate** NanoZoomer S360MD Slide scanner system (K213883)
Image File Formats	SVS, NDPI	SVS, DICOM	NDPI
Image Manipulation 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
Type of Software Application	Internet browser based	Internet browser based	Windows based
Principle of Operation	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 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	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 microimages, 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.	The NanoZoomer S360MD Slide Scanner System by Hamamatsu Photonics is an automated digital slide creation, viewing, and management system designed for in vitro diagnostic use. It assists pathologists in reviewing and interpreting digital images of surgical pathology slides prepared from formalin-fixed paraffin-embedded (FFPE) tissue. Principle of Operation: Slide Loading: The system accommodates up to 360 standard-sized slides (25.0 mm to 26.0 mm × 75.0 mm to 76.0 mm) organized in 12 cassettes, each holding 30 slides. Barcode and Macro Imaging: Each slide is first subjected to barcode scanning and macro imaging to capture an overview of the tissue and identify areas of interest. Micro Imaging: The slide is then moved to the micro imaging position, where a 20× objective lens (NA 0.75) and a CMOS camera capture high-resolution images. The system automatically detects focusing points and scans the slide to acquire the digital image. Image Processing: The captured images are stitched together to create a single composite high-resolution image. Images are automatically saved to the

	Subject Device ViraSight (K251952)	**Primary Predicate** Aperio GT 450 DX (K232202)	**Secondary Predicate** NanoZoomer S360MD Slide scanner system (K213883)
	adjustment of image to edit brightness and contrast		system's hard disk and can be viewed using the NZViewMD software. Software Integration: The NZViewMD software allows for continuous panning and zooming, comparison of multiple slide images simultaneously, creation of annotations, tracking of visited areas, and digital bookmarks. The NanoZoomer S360MD Slide Scanner System is intended for use with FFPE tissue slides and is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens.

PERFORMANCE DATA

A series of tests were performed to assess the safety and effectiveness of ViraSight. All the test results demonstrate that the subject device meets the requirements of its pre-defined acceptance criteria and intended use.

The following performance tests were conducted per FDA guidance "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Device (2016)" and "Applying Human Factors and Usability Engineering to Medical Devices (2016)".

<table>
<tr><th>Test</th><th>Result</th></tr>
<tr><td>Pixel-wise Comparison</td><td>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 FDA guidance document, "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices" dated April 20, 2016") as described below for the same image file format generated from the same intended use scanner to validate equivalent image reproduction on the same intended display.
<table>
<tr><th>Display</th><th>Scanner</th><th>Image File Format</th><th>Comparator</th><th>Browser</th></tr>
</table>
</td></tr>
</table>

Test	Result
	<table><tr><td rowspan="4">Dell U3023E</td><td rowspan="2">Hamamatsu NanoZoomer S360MD Scanner</td><td rowspan="2">NDPI</td><td rowspan="2">Hamamatsu NZViewMD</td><td>Chrome</td></tr><tr><td>Edge</td></tr><tr><td rowspan="2">Leica Aperio GT450 DX Scanner</td><td rowspan="2">SVS</td><td rowspan="2">Leica Aperio WebViewer DX</td><td>Chrome</td></tr><tr><td>Edge</td></tr></table> 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. The slides scanned with the Leica Aperio GT 450 DX scanner were saved in SVS format, while the slides scanned with the Hamamatsu NanoZoomer S360MD scanner were saved in NDPI format. For each WSI dataset, three rectangular regions of interest (ROIs) were identified per slide for each tested viewer zoom level. Screenshots of these ROIs were captured at two viewer zoom levels, 20x and 40x, using 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, ViraSight screenshots captured in Google Chrome and Microsoft Edge were compared against Hamamatsu NZViewMD screenshots. The testing process ensured comprehensive evaluation across scanner file formats, viewer zoom levels, and supported browser conditions. The raw 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 (ΔE00) metric through the FDA qualified medical device development tool (MDDT) IVIES. The acceptance criterion for this testing required that the 95th percentile of the pixel-wise color differences in every ROI image pair between ViraSight and the applicable reference viewer must be less than 3 CIEDE2000 (i.e., < 3 ΔE00) to be considered acceptable. Test results showed that the maximum 95th percentile of pixel-wise differences between ViraSight and the reference viewers was less than 3 CIEDE2000 across all comparison sets. No tested ROI image pair exceeded the ΔE00 = 3 threshold at the 95th percentile, indicating that ViraSight output images were visually consistent with the applicable reference viewers for both supported scanner file formats. Therefore, it was determined that color images reproduced by ViraSight were visually adequate with respect to its intended use.
Measurements of area and distance	Measurement accuracy testing was performed to demonstrate that ViraSight accurately represents length and area measurements across the supported scanner file formats,

<table>
<tr><th>Test</th><th>Result</th></tr>
<tr><td></td><td>
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 for the testing. 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 verified 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. Test results as listed in Table 1 show that the pre-specified acceptance criterion of <0.01% difference between the ViraSight-generated measurement and the applicable reference value was met. All completed measurement records were exact matches with no error. The subject device performed accurate length and area measurements across the tested configurations with respect to its intended use.

Table 4. ViraSight Measurement Results
<table>
<tr><th rowspan="2">Scanner</th><th rowspan="2">Image Format</th><th rowspan="2">Subject Device / Browser</th><th colspan="2">Percent Difference (%)</th></tr>
<tr><th>Length Measurement</th><th>Area Measurement</th></tr>
<tr><td rowspan="2">Leica Aperio GT 450 DX scanner</td><td rowspan="2">SVS</td><td>ViraSight / Chrome</td><td>0</td><td>0</td></tr>
<tr><td>ViraSight / Edge</td><td>0</td><td>0</td></tr>
<tr><td rowspan="2">Hamamatsu NanoZoomer S360MD Slide scanner</td><td rowspan="2">NDPI</td><td>ViraSight / Chrome</td><td>0</td><td>0</td></tr>
<tr><td>ViraSight / Edge</td><td>0</td><td>0</td></tr>
</table>
</td></tr>
<tr><td>Turnaround Time</td><td>Turnaround times (TAT) for image loading, panning, and zooming were tested with ViraSight when using all supported browsers, as listed in Table 2 below. 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. Each browser/file-format configuration was tested in two independent runs using WSIs over a range of file sizes.</td></tr>
</table>

<table>
<tr><th>Test</th><th>Result</th></tr>
<tr><td></td><td>
The purpose of the testing was to demonstrate that ViraSight provides acceptable image rendering performance for the intended use of the subject device. Turnaround time values were recorded for WSI loading, 20X zooming, 40X zooming, and panning. All tested WSIs loaded successfully, and zooming and panning operations were completed without rendering failure, application crash, loss of image data, or interruption preventing intended use. Test results showed acceptable turnaround time performance for the intended use of the subject device, as shown in Table 5 below.

Table 5. ViraSight Turnaround Time Testing Results
<table>
<tr><th rowspan="2">Scanner</th><th rowspan="2">Image File Format</th><th rowspan="2">Subject Device / Browser</th><th colspan="4">Results (Sec)</th></tr>
<tr><th>Loading</th><th>20X Zooming</th><th>40X Zooming</th><th>Panning</th></tr>
<tr><td rowspan="2">Leica Aperio GT 450 DX scanner</td><td rowspan="2">SVS</td><td>ViraSight / Chrome</td><td>Mean = 1.032
Range = 0.594–1.717</td><td>Mean = 1.655
Range = 0.553–3.343</td><td>Mean = 0.403
Range = 0.014–3.595</td><td>Mean = 0.172
Range = 0.062–0.504</td></tr>
<tr><td>ViraSight / Edge</td><td>Mean = 0.952
Range = 0.653–1.839</td><td>Mean = 1.084
Range = 0.081–2.304</td><td>Mean = 0.192
Range = 0.057–2.018</td><td>Mean = 0.104
Range = 0.020–0.363</td></tr>
<tr><td rowspan="2">Hamamatsu NanoZoomer S360MD Slide scanner</td><td rowspan="2">NDPI</td><td>ViraSight / Chrome</td><td>Mean = 0.833
Range = 0.664–1.178</td><td>Mean = 1.970
Range = 0.845–3.137</td><td>Mean = 0.224
Range = 0.076–0.942</td><td>Mean = 0.116
Range = 0.062–0.286</td></tr>
<tr><td>ViraSight / Edge</td><td>Mean = 0.869
Range = 0.675–1.407</td><td>Mean = 1.727
Range = 0.409–2.960</td><td>Mean = 0.248
Range = 0.058–0.807</td><td>Mean = 0.145
Range = 0.075–1.345</td></tr>
</table>

Turnaround time testing demonstrated that ViraSight provided acceptable image loading/rendering, zooming, and panning performance across the tested scanner file formats and supported browser environments with respect to its intended use.
</td></tr>
</table>

Test	Result
Human factors testing	A human factors study designed around critical user tasks and use scenarios performed by representative users was conducted per FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices (2016)". ViraSight 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 ViraSight is substantially equivalent to the previously cleared predicate devices, when used with the Hamamatsu NanoZoomer S360MD Slide scanner or Leica Aperio GT 450 DX and JVC Kenwood JD-C240BN01A, BARCO MDPC-8127, Dell UP3017, Dell U3023E, and Dell U3223QE display monitors. Performance Data demonstrate Substantial Equivalence of the device.