510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A. 510(k) Number

K253554

B. Applicant

Leica Biosystems Imaging, Inc.

C. Proprietary and Established Names

Aperio GT 450 DX
Aperio GT 180 DX

D. Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PSY	Class II	21 CFR 864.3700	88-Pathology

II Submission/Device Overview:

A Purpose for Submission:

1. New device - Aperio GT 180 DX
2. Add 5 new software features to Aperio GT 450 DX cleared in K232202.
3. Establish a Pre-Determined Change Control Plan (PCCP; version 01) for qualifying and adding additional FDA-cleared displays as interoperable components to the Aperio GT 450 DX and Aperio GT 180 DX.

B Type of Test:

Digital pathology whole slide imaging

III Intended Use/Indications for Use:

A Intended Use(s):

Aperio GT 450 DX Intended Use

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.

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.

Aperio GT 180 DX Intended Use

The Aperio GT 180 DX is an automated digital slide creation and viewing system. The Aperio GT 180 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 180 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.

The Aperio GT 180 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 180 DX.

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:

Aperio GT 450 DX

Aperio GT 450 DX is comprised of the Aperio GT 450 DX scanner and corresponding scanner configuration software, Aperio Scanner Administration Manager DX (SAM DX). The scanner 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 an interoperable display that has been 510(k) cleared for use with Aperio GT 450 DX or a 510(k) cleared display that has been assessed in accordance with the PCCP for qualifying additional interoperable 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

Scanner Hardware	Scanner Output File Format	Interoperable Viewing Software	Interoperable Displays
Aperio GT 450 DX scanner	SVS	Aperio WebViewer DX	DELL UP3017 Dell U3023E Dell U3223QE Barco MDPC-8127 Additional displays validated per the authorized PCCP
	SVS	Sectra Digital Pathology Module (3.3)	
	DICOM	Sectra Digital Pathology Module (3.3)	
	DICOM	Aperio WebViewer DX	

Compared to the previously cleared Aperio GT 450 DX, the following new functions were added to Aperio GT 450 DX by modifying the software only:

- Auto Narrow Stripe
- Extended Focus
- Manual Scan
- 20X Imaging
- Z-Stacking

Aperio GT 180 DX

Aperio GT 180 DX is comprised of the Aperio GT 180 DX scanner and corresponding scanner configuration software, Aperio Scanner Administration Manager DX (SAM DX). The scanner 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 an interoperable display that has been 510(k) cleared for use with Aperio GT 180 DX or a 510(k) cleared display that has been assessed in accordance with the PCCP for qualifying additional interoperable displays. The Aperio GT 180 DX is intended to be used with the interoperable components specified in Table 2.

Table 2: Interoperable components of Aperio GT 180 DX

Scanner Hardware	Scanner Output File Format	Interoperable Viewing Software	Interoperable Displays
Aperio GT 180 DX scanner	SVS	Aperio WebViewer DX	DELL UP3017 Dell U3023E Dell U3223QE Barco MDPC-8127 Additional displays validated per the authorized PCCP
	SVS	Sectra Digital Pathology Module (3.3)	
	DICOM	Sectra Digital Pathology Module (3.3)	
	DICOM	Aperio WebViewer DX	

The Aperio GT 180 DX includes the following additional functions:

- Auto Narrow Stripe

- Extended Focus
- Manual Scan
- 20X Imaging
- Z-Stacking

Image Acquisition Subsystem

The Aperio GT 450 DX scanner and Aperio GT 180 DX scanner are semi-automated benchtop brightfield WSI scanners. The scanners support continuous glass-slide loading, priority rack scanning, and automated image quality checks during image acquisition. The scanners detect the racks once loaded in the scanner and scan the slides automatically. Users operate the scanner via a touchscreen interface.

Digital images are saved by the scanners in the unique Aperio ScanScope Virtual Slide (.svs) image format or the Digital Imaging and Communications in Medicine (DICOM) image format. The digital images are sent to end-user-provided image storage attached to the scanner's local network, where they can be cataloged in image storage software (external to the subject device), including Image Management System (IMS), such as Aperio eSlide Manager, or Picture Archiving and Communication System (PACS), such as Sectra PACS software (external to the subject device).

Aperio SAM DX is centralized scanner management software that operates externally to the connected scanner(s). This software application enables IT implementation, including configuration, monitoring, and service access of multiple scanners from a single desktop client location. Aperio SAM DX is installed on a customer-provided server that resides on the same network as the scanner(s) for image management.

Image Viewing Subsystem

The image viewing subsystem of the WSI device displays digital images to the human reader. This subsystem comprises Aperio WebViewer DX image viewing software, a workstation personal computer (PC), and interoperable display(s). The Aperio WebViewer DX software is a web-based image viewer that enables users to visually perform Quality Control of images and to review and annotate digital images for routine diagnosis. The Aperio WebViewer DX also incorporates monitor display image validation checks, which provide the user with the ability to ensure the digital slide images are displayed as intended on their display, and that browser updates have not inadvertently affected the image display quality. Aperio WebViewer DX is installed on a server and accessed from an IMS (e.g., Aperio eSlide Manager) or a customer's Laboratory Information System (LIS) using compatible browsers.

Instrument Description Information:

a. Instrument Name:
Aperio GT 450 DX
Aperio GT 180 DX

b. 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 surgical pathology slides prepared from FFPE tissue.

c. 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 Aperio GT Platform.

d. Calibration:
The Aperio GT 450 DX and GT 180 DX perform essential image calibrations at the time the scanner is powered on. No additional calibration is needed for regular use. There is no calibration for scanner software.

e. Quality Control:
Quality control (QC) activities are performed by the user per the laboratory standards and professional guidelines (e.g., staining, cover-slipping, barcode placement) prior to loading the slides into the scanners. After completing a scan, the lab technician checks image data and image quality as per the instructions for use. Before review, the pathologist performs quality control on the WSI images of the slide per instructions for use.

V Substantial Equivalence Information :

A Predicate Device Name(s):

Aperio GT 450 DX

B Predicate 510(k) Number(s):

K232202

C Comparison with Predicate(s):

The subject device is similar to the predicate, having similar indications for use, intended use, technological characteristics as its predicate device, other than implementation of a Predetermined Change Control Plan (PCCP) that specifies the protocols and acceptance criteria for validating and adding additional FDA-cleared displays as interoperable component to the Aperio GT 450 DX and Aperio GT 180 DX in a controlled manner, such that the device is as safe and as effective as the predicate.

The sponsor's PCCP for validating the use of additional FDA-cleared display is part of the Leica Biosystems Imaging, Inc. quality management system and comprises the following phases:

1. When a new FDA-cleared display is identified as the candidate, the candidate display, and its supplier will be evaluated based on various considerations. A design change request will be generated if the candidate display and its supplier pass the evaluation.

2. The candidate display will be tested with a set of FDA-approved system-level integration test methods and acceptance criteria, for the complete WSI system specified in the PCCP. The tests will be conducted by a qualified tester according to the quality management system. If there is a failure detected during the test, the failure(s) will be recorded, and the design change will not be implemented.
3. If the candidate display meets the acceptance criteria, the design change will be implemented according to the quality management system, and the new display may be added as an interoperable component to the Aperio GT 450 DX and Aperio GT 180 DX scanner system without additional premarket review.
4. Any display-specific software will be verified by Leica Biosystems Imaging, Inc. to confirm it does not impact performance of the Aperio GT 450 DX and Aperio GT 180 DX scanner systems.
5. The system labeling and company website will be revised to identify the new display according to the quality management system.

The similarities and differences between the subject and predicate devices are summarized in Table below.

Device & Predicate Device(s):	**K232202** Aperio GT 450 DX (Predicate Device)	**K253554** Aperio GT 450 DX (Subject Device)
General Device Characteristics: Similarities		
Intended Use	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	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. 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.

<table>
<tr><th>Device & Predicate Device(s):</th><th>K232202
Aperio GT 450 DX
(Predicate Device)</th><th>K253554
Aperio GT 450 DX
(Subject Device)</th></tr>
<tr><td></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 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></td></tr>
<tr><td>Principle of Operation</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 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.</td><td>Same</td></tr>
<tr><td>Device Components</td><td>WSI scanner (Aperio GT 450 DX scanner), Image Management System (Aperio WebViewer DX image viewing software) and color monitor display</td><td>WSI scanner (Aperio GT 450 DX scanner), Image Management System (Aperio WebViewer DX image viewing software v1.2) and color monitor display</td></tr>
<tr><td>Image Storage</td><td>Images are stored in the end-user- provided image storage attached to the local network.</td><td>Same</td></tr>
<tr><td>Scanning</td><td>40x</td><td>Same</td></tr>
</table>

Device & Predicate Device(s):	K232202 Aperio GT 450 DX (Predicate Device)	K253554 Aperio GT 450 DX (Subject Device)
Magnification		
General Device Characteristics: Differences		
Z-Stacking Feature	No	Yes
Auto Narrow Stripe Feature	No	Yes
Extended Focus Feature	No	Yes
Manual Scan Feature	No	Yes
20x Imaging	No	Yes
Interoperable Display (Monitor)	DELL UP3017 Dell U3023E Dell U3223QE Barco MDPC-8127	DELL UP3017 Dell U3023E Dell U3223QE Barco MDPC-8127 +PCCP
Aperio WebViewer - Compatible File Format	SVS	SVS and DICOM
Viewer – Image Compression type	Lossy	Lossy and Lossless

Equivalency between Aperio GT 450 DX and Aperio GT 180 DX

The sponsor provided information on modifications made to Leica Aperio GT 450 DX and to establish equivalency between Leica Aperio GT 450 DX and Leica Aperio GT 180 DX. The following items are present and acceptable.

1. Comparison information (i.e., similarities and differences) to the submitter's legally marketed predicate device, including trade name, 510(k) number, indications for use/intended use, labeling, and principles of operation.
2. Detailed design documentation, including engineering drawings, labeled diagrams, technical specifications, part numbers, and bill of materials, was provided to demonstrate that the pixel pipelines are identical between the Leica Aperio GT 450 DX and Leica Aperio GT 180 DX systems. Specifically, the following aspects of the pixel pipeline were addressed:
    a. Components in the pixel pipeline, including the light source, imaging optics (objective and tube lens), digital image sensor (camera and frame grabber), image processing software (Scanner Control Software), image composition

software (DICOM service and SAM software), and image review/manipulation software (WebViewer software).

b. Boundary of the pixel pipeline, including hardware interfaces (Autoloader firmware and Acquisition Services) and software interfaces inside Scanner Control Software.
c. The same XY stage, Z stage, autoloader, macro lens, and macro light source are used in both scanners. A smaller carousel baseplate is used in the Leica Aperio GT 180 DX.
d. The differences between the two scanners are outside the pixel pipeline and will not affect the image quality.

<table>
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Aperio GT 450 DX
(Predicate Device)</th><th>K253554
Aperio GT 180 DX
(Subject Device)</th></tr>
<tr><td colspan="3">General Device Characteristics: Similarities</td></tr>
<tr><td>Intended Use</td><td>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
<table><tr><th>Scanner Hardware</th><th>Scanner Output file format</th><th>Interoperable Viewing Software</th><th>Interoperable Displays</th></tr></table></td><td>The Aperio GT 180 DX is an automated digital slide creation and viewing system. The Aperio GT 180 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 180 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. The Aperio GT 180 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 180 DX.</td></tr>
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<tr><th>Device & Predicate Device(s):</th><th>K232202
Aperio GT 450 DX
(Predicate Device)</th><th>K253554
Aperio GT 180 DX
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<tr><td>Aperio GT 450 DX scanner</td><td>SVS</td><td>Aperio WebViewer DX</td><td>Barco MDPC-8127
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<tr><td>Aperio GT 450 DX scanner</td><td>DICOM</td><td>Sectra Digital Pathology Module (3.3)</td><td>Dell U3223QE</td></tr>
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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.
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<tr><td>Principle of Operation</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 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.</td><td>Same</td></tr>
<tr><td>Image Storage</td><td>Images are stored in the end-user- provided image storage attached to the local network.</td><td>Same</td></tr>
<tr><td>Scanning Magnification</td><td>40x</td><td>Same</td></tr>
<tr><td colspan="3">General Device Characteristics: Differences</td></tr>
<tr><td>Slide Storage/loading Capacity</td><td>450 slides, 1x 3 inch slide</td><td>180 slides, 1x 3 inch slide</td></tr>
<tr><td>Device Components</td><td>WSI scanner (Aperio GT 450 DX scanner), Image Management System (Aperio WebViewer DX image viewing software) and color monitor</td><td>WSI scanner (Aperio GT 180 DX scanner), Image Management System (Aperio WebViewer DX image</td></tr>
</table>

Device & Predicate Device(s):	K232202 Aperio GT 450 DX (Predicate Device)	K253554 Aperio GT 180 DX (Subject Device)
	display	viewing software v1.2) and color monitor display
Compatible Display (Monitor)	DELL UP3017 Dell U3023E Dell U3223QE Barco MDPC-8127	DELL UP3017 Dell U3023E Dell U3223QE Barco MDPC-8127 Additional displays validated per the authorized PCCP
Aperio WebViewer - Compatible File Format	SVS	SVS and DICOM

VI Standards/Guidance Documents Referenced:

1. FDA Guidance "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices" dated 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. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Guidance for Industry and Food and Drug Administration Staff, May 2005.
4. IEC/EN 61010-1:2010/AMD1: 2016, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements.
5. IEC/EN 61010-2-101: 2018, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.
6. FDA Guidance "Electromagnetic Compatibility (EMC) of Medical Devices" (June 6, 2022).

VII Performance Characteristics (if/when applicable):

A **Analytical Performance:**

1. Precision/Reproducibility:
   The precision study was previously conducted for the predicate device (K232202) per the Special Control in 21 CFR 864.3700(b)(1)(iv)(A) and 864.3700(b)(1)(iv) (B). A new precision study was not conducted for the current device [Aperio GT 450 DX and Aperio GT 180 DX] since there are no changes between the predicate device and the subject device in the hardware, optical path, critical components and interoperability with the viewing software. The subject device includes only software modifications when compared to the predicate device.

2. Linearity:
   Not applicable

3. Analytical Specificity/Interference:
   Not applicable

4. Accuracy (Instrument):
   Not applicable

5. Carry-Over:
   Not applicable

B. **Technical Studies:**

Multiple studies were conducted to evaluate the performance of the Aperio GT 450 DX and Aperio GT 180 DX as recommended in FDA Guidance, *Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices.*

a. Slide Feeder

Information was provided on the configuration of the slide feed mechanism, including a physical description of the slide, the number of slides in the queue (carrier), and the class of automation. Information was provided on the user interaction with the slide feeder, including hardware, software, feedback mechanisms, and Failure Mode and Effects Analysis (FMEA).

b. Light source

Descriptive information associated with the lamp and the condenser was provided. Testing information was provided to verify the spectral distribution of the light source as part of the color reproduction capability of the Aperio GT 450 DX scanner.

c. Imaging optics

An optical schematic with all optical elements identified from the slide (object plane) to the digital image sensor (image plane) was provided. Descriptive information regarding the microscope objective, the auxiliary lenses, and the magnification of imaging optics was provided. Testing information regarding the relative irradiance, optical distortions, and lateral chromatics aberrations was provided.

d. Mechanical scanner movement

Information and specifications on the configuration of the stage, method of movement, control of movement of the stage, and FMEA were provided. Test data to verify the repeatability of the stage movement and verify the mechanism that the stage movement stays within limits during operations was provided.

e. Digital imaging sensor

Information and specifications on the sensor type, pixel information, responsivity specifications, noise specifications, readout rate, and digital output format were provided. Test data to determine the correct functioning of the digital image sensor was provided. The digital image sensor converts slides' optical signals to digital signals. The digital signals consist of a set of numerical values corresponding to the brightness and color at each point in the optical image.

f. Image processing software

Information and specifications on exposure control, white balance, color correction, sub-

sampling, pixel-offset correction, pixel-gain or flat-field correction, and pixel-defect correction were provided.

g. *Image composition*
Information and specifications on the scanning method, the scanning speed, and the number of planes at the Z-axis to be digitized were provided. Test data to analyze the image composition performance was provided.

h. *Image files format*
Information and specifications on the compression method, compression ratio, file format, and file organization were provided.

i. *Image review manipulation software*
Information and specifications on continuous panning and pre-fetching, continuous zooming, discrete Z-axis displacement, the ability to compare multiple slides simultaneously on multiple windows, image enhancement and sharpening functions, color manipulation, annotation tools, and digital bookmarks were provided.

j. *Computer environment*
Information and specifications on the computer hardware, operating system, graphics card, graphics card driver, color management settings, color profile, and display interface were provided.

k. *Display*
Information and specifications on the technological characteristics of the display device, the physical size of the viewable area and aspect ratio, backlight type and properties, frame rate and refresh rate, a pixel array, pitch, pixel aperture ratio, and subpixel matrix scheme, subpixel driving to improve grayscale resolution, supported color spaces, display interface, user controls of brightness, contrast, gamma, color space, power-saving options, etc., via the on-screen display menu, ambient light adaptation, touchscreen technology, color calibration tools, and frequency and nature of quality-control tests were provided. Test data to verify the performance of the display was provided.

l. *Color reproducibility*
Test data to evaluate the color reproducibility of the system was provided.

m. *Spatial resolution*
Test data to evaluate the composite optical performance of all components in the image acquisition phase was provided.

n. *Focusing test*
Test data to evaluate the technical focus quality of the system was provided.

o. *Whole slide tissue coverage*
Test data to demonstrate that the entire tissue specimen on the glass slide is detected by the tissue detection algorithms and that all the tissue specimens are included in the digital image file was provided.

p. *Stitching error*
Test data to evaluate the stitching errors and artifacts in the reconstructed image was provided.

q. *Turnaround time*
Test data to evaluate the turnaround time of the system was provided.

r. *Pixel-Wise Comparison Study*
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)] to demonstrate that the Aperio WebViewer DX version 1.2 (Subject Viewer) can decode input image files and display pixelwise identical images when compared to the Aperio WebViewer DX version 1.0 (reference viewer or predicate Viewer). For each image-pair, the pixelwise differences between two images were calculated using the CIEDE2000 color difference metric. Two images were identical if the 95th percentile of the pixelwise color differences is less than 3 CIEDE2000 (< 3 ΔE00). A configuration can be validated if all image-pairs are identical to the reference configuration. Based on analysis of the testing data (Please see the Table 3 below), the multiple testing features and their pixelwise difference between the file image formats when displayed in Aperio WebViewer DX (v1.2) were identical, i.e., < 3 ΔE00 to the reference viewer.

Table 3: Pixel-wise Comparison Test Results

Scanner	File Format	Comparator/ Predicate device IRMS Subject Device/ Browser	Pixel-Wise Comparison Results, ΔE00 (min, max, mean) Slides: 30 Regions of Interest (ROIs): 3 Browsers: Chrome and Edge
Leica Aperio GT 450 DX Scanner	SVS	Aperio WebViewer DX (v1.0)	20x-40x: 0.00, 0.00, 0.00 10x-20x: 0.00, 0.00, 0.00
		Aperio WebViewer DX (v1.2)	
Leica Aperio GT 450 DX Scanner	SVS	Aperio WebViewer DX (v1.0)	20x-40x: 0.73, 2.09, 1.25 10x-20x: 0.82, 2.12, 1.30
	DICOM	Aperio WebViewer DX (v1.2)	
Leica Aperio GT 450 DX Scanner [Z-Stacking]	SVS	Aperio WebViewer DX (v1.0)	20x-40x: 0.00, 0.00, 0.00
		Aperio WebViewer DX (v1.2)	
Leica Aperio GT 450 DX [Extended Focus]	SVS	Aperio WebViewer DX (v1.0)	20x-40x: 0.00, 0.00, 0.00
		Aperio WebViewer DX (v1.2)	

C. Clinical Studies:

The clinical study performed as part of K232202 is being leveraged for Aperio GT 450 DX and Aperio GT 180 DX. No new clinical study was performed, since there are no changes between the predicate device and the subject device in hardware, optical path, critical components and interoperability with the viewing software.

D. Human Factor Study:

Human factors studies for the Aperio GT 450 DX and Aperio GT 180 DX were conducted. The studies were designed around critical user tasks and use scenarios performed by representative users. The information included a list of all critical user tasks and a description of the process used to identify them. A systematic evaluation involving simulated use by representative users performing all tasks (including critical tasks) required for the operation of the device and a subjective assessment of failure was provided. Most participants were able to perform the tasks

successfully, with 14 out of 16 critical tasks completed by all users. There were occasional difficulties resulting in assisted or unresolved outcomes for two tasks, which did not indicate a safety failure and were attributed to a software defect that has since been resolved with no residual risks. The learnability and ease of use were considerably high and there were no difficulties or failures observed on tasks that could lead to patient harm. In all instances, the representative users were able to identify cases and ensure their completeness.

VIII Pre-determined Change Control Plan (PCCP):

Leica Biosystems Imaging, Inc. provided a PCCP (version 01) and is authorized as part of this 510(k) clearance. When a new FDA-cleared display is identified to be added as an interoperable display, it will be verified and validated in accordance with a system-level integration test which will also be conducted to confirm that the new display functions adequately with the complete WSI system, including the original scanner and viewer components. Following successful validation, Leica Biosystems Imaging, Inc. will update the device labeling in accordance with the authorized PCCP to ensure that users are provided with accurate and current information regarding display compatibility. If the candidate display meets the criteria defined in the PCCP, the design change will be implemented according to the quality management system and the new display may be added as an interoperable component to the subject device without additional premarket review. Leica Biosystems Imaging, Inc. will revise the device labeling and company website to identify the new display according to the PCCP.

IX Proposed Labeling:

The labeling is sufficient, and supports the finding of substantial equivalence for Aperio GT 450 DX and Aperio GT 180 DX

X Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision to the predicate device cleared in K232202.