Leica Biosystems Imaging, Inc.
April Komplin, MS
Senior Manager, Regulatory Affairs
1360 Park Center Dr.
Vista, CA 92081

August 7, 2026

Re: K253554
Trade/Device Name: Aperio GT 450 DX
Aperio GT 180 DX
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: PSY
Dated: November 14, 2025
Received: November 14, 2025

Dear April Komplin:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253554

Device Name
Aperio GT 450 DX
Aperio GT 180 DX

Indications for Use *(Describe)*

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.

Aperio GT 180 DX:

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary
Aperio GT 450 DX
Aperio GT 180 DX

Date Prepared: July 22, 2026

Submitter
Leica Biosystems Imaging, Inc
1360 Park Center Dr., Vista, CA 92081

Contact

Primary Contact
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Device Information

Subject Device: Aperio GT 450 DX

Device Trade/Proprietary Name:	Aperio GT 450 DX
Device Common or Usual Name:	Aperio GT 450 DX
Device Classification Name:	Whole Slide Imaging System
Device Regulatory Classification:	Class II
Device Classification Regulation:	21 CFR §864.3700
Product Code:	PSY
Classification Panel:	Pathology
Manufacturer:	Leica Biosystems Imaging, Inc.

Predicate Device for Aperio GT 450 DX:

Device Trade/Proprietary Name:	Aperio GT 450 DX
510(k) Number:	K232202

Subject Device: Aperio GT 180 DX

Device Trade/Proprietary Name:	Aperio GT 180 DX
Device Common or Usual Name:	Aperio GT 180 DX
Device Classification Name:	Whole Slide Imaging System
Device Regulatory Classification:	Class II
Device Classification Regulation:	21 CFR §864.3700
Product Code:	PSY
Classification Panel:	Pathology
Manufacturer:	Leica Biosystems Imaging, Inc.

Predicate Device for Aperio GT 180 DX:

Device Trade/Proprietary Name:	Aperio GT 450 DX
510(k) Number:	K232202

I. 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.

II. 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.

III. Purpose of the Submission:

- New software features added to Aperio GT 450 DX cleared under K232202.
- New Device: Aperio GT 180 DX.
- 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.

IV. Device Description

Aperio GT 450 DX and Aperio GT 180 DX are referred to as the Aperio GT Platform in this document.

Aperio GT 450 DX is a WSI system comprised of an image acquisition subsystem known as the Aperio GT 450 DX scanner and Aperio WebViewer DX image viewing software which is accessed from a workstation and a display.

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 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 Predetermined Change Control Plan (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**
Aperio GT 450 DX scanner	SVS	Aperio WebViewer DX
	SVS	Sectra Digital Pathology Module (3.3)
	DICOM	Sectra Digital Pathology Module (3.3)
	DICOM	Aperio WebViewer DX

Aperio GT 180 DX is a WSI system comprised of an image acquisition subsystem known as the Aperio GT 180 DX scanner and Aperio WebViewer DX image viewing software which is accessed from a workstation and a display.

Aperio GT 180 DX is comprised of the Aperio GT 180 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 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 Predetermined Change Control Plan (PCCP) for qualifying additional interoperable displays. The Aperio GT 180 DX is intended to be used with the interoperable components specified in Table 1.

Table 2: Interoperable components of Aperio GT 180 DX

Scanner Hardware	**Scanner Output File Format**	**Interoperable Viewing Software**
Aperio GT 180 DX scanner	SVS	Aperio WebViewer DX
	SVS	Sectra Digital Pathology Module (3.3)
	DICOM	Sectra Digital Pathology Module (3.3)

Compared to the previously cleared Aperio GT 450 DX, the following new functions were added to both Aperio GT 450 DX and Aperio GT 180 DX scanners by modifying software only:

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

1) Image Acquisition Subsystem

The image acquisition subsystem of the Aperio GT Platform (Including both Aperio GT 450 DX and Aperio GT 180 DX) captures the information from surgical pathology glass slides prepared from FFPE tissue and saves it as a high-resolution digital image file. This subsystem consists of the Aperio GT Platform scanner and corresponding scanner configuration software, Aperio Scanner Administration Manager DX (SAM DX).

The Aperio GT 450 Platform scanner is a semi-automated benchtop brightfield WSI scanner. The scanner supports continuous glass-slide loading, priority rack scanning, and automated image quality checks during image acquisition. The Aperio GT Platform scanner can be used with LBS-manufactured slide racks (Product No. 23RACKGT450) and other supported slide racks (e.g., Prisma® 20-slide basket from Sakura Finetek USA, Inc). The Aperio GT Platform scanner detects the racks once loaded in the scanner and scans the slides automatically. Users operate the scanner via a touchscreen interface.

The Aperio GT Platform scanner can save digital images 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 (Non-medical device, external to the WSI), including Image Management System (IMS), such as Aperio eSlide Manager, or Picture Archiving and Communication System (PACS), such as Sectra PACS software (not included in this submission)

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.

2) 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 PC, and monitor(s). Both the workstation and display are procured by the customer from commercial distributors. The Aperio WebViewer DX software is a web-based image viewer that enables users to 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 monitor, 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 interoperable browsers.

V. Comparison of technological characteristics with the predicate device

The substantial equivalence comparisons for both subject devices are shown in **Tables 1-4.**

Table 1. Similarities between Aperio GT 450 DX Modification and the Predicate Device

Item	Predicate Device	Subject Device	Note
Product Name	Aperio GT 450 DX	Aperio GT 450 DX	-
510(k) No.	K232202	K253554	-
Manufacturer	Leica Biosystems Imaging, Inc.	Leica Biosystems Imaging, Inc.	Same
Device Photo			-
Classification Regulation	21 CFR 864.3700	21 CFR 864.3700	Same
Product Code	PSY – Whole Slide Imaging System	PSY – Whole Slide Imaging System	Same
Classification Panel	(88) Pathology	(88) Pathology	Same
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	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	Similar Added PCCP Added DICOM in Aperio WebViewer DX

<table>
<tr><td></td><td>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><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>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.</td><td></td></tr>
<tr><td>Intended Users</td><td>Trained pathologists and clinical pathology histotechnicians</td><td>Trained pathologists and clinical pathology histotechnicians</td><td>Same</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</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,</td><td>Same</td></tr>
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	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.	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.	
Prescription Use	Prescription Use Only	Prescription Use Only	Same
Use Environment	Clinical laboratory	Clinical laboratory	Same
Specimen Type	Formalin-Fixed Paraffin-Embedded (FFPE) Specimen	Formalin-Fixed Paraffin-Embedded (FFPE) Specimen	Same
Touchscreen Size	10.1 inches	10.1 inches	Same
Tissue Finding	Automatic	Automatic	Same
Focusing System	Automatic	Automatic	Same
Supported slide size	1 x 3 inch	1 x 3 inch	Same
Slide Loading Method	Automatic and Manual	Automatic and Manual	Same
Continuous Loading	Yes	Yes	Same
Rack position angle	5 degrees	5 degrees	Same
Scanning Magnification	40x	40x	Same
Scanning Resolution at 40x	0.26 µm/pixel	0.26 µm/pixel	Same
Scanning Region	≤ 23.6 mm x 58 mm for 1x 3 inch slide	≤ 23.6 mm x 58 mm for 1x 3 inch slide	Same
Scan Speed at 40x	< 32 sec/slide, 15 x 15 mm	<32 sec/slide, 15 x 15 mm	Same

Scan Output Image Format	.svs and DICOM	.svs and DICOM	Same
Pusher-puller travel distance	95.15 mm	95.15 mm	Same
Pusher-puller height	130 mm (from scanner base plate to the bottom of pusher)	130 mm (from scanner base plate to the bottom of pusher)	Same
Auto QC During Scanning	Yes	Yes	Same
Focusing Resolution at 40x	+/- 0.125 micron	+/- 0.125 micron	Same
Focusing error at 40x	+/- 0.5 micron	+/- 0.5 micron	Same
Focusing method	Real-Time focus and point focus	Real-Time focus and point focus	Same
Objective lens	40x/0.65 Plan Apo wide field	40x/0.65 Plan Apo wide field	Same
Color Reproducibility	Max $\Delta E < 10$	Max $\Delta E < 10$	Same
Image Storage	Images are stored in the end-user-provided image storage attached to the local network.	Images are stored in an end user-provided image storage attached to the local network.	Same
Throughput (includes slide handling) at 40x	81 slides per hour	81 slides per hour	Same
Turnaround Time	Within 3 seconds until the image is fully loaded.	Within 3 seconds until the image is fully loaded.	Same
Image Manipulation Functions	Panning, zooming, gamma function, annotations, and measurements (distance)	Panning, zooming, gamma function, annotations, and measurements (distance)	Same
Type of viewer Software Application	Web-based application	Web-based application	Same
Compatible Viewers	Aperio WebViewer DX Sectra Digital Pathology Module 3.3	Aperio WebViewer DX Sectra Digital Pathology Module 3.3	Same
Slide Storage/loading Capacity	450 slides, 1x 3 inch slide	450 slides, 1x 3 inch slide	Same

Device Weight	63.5kg	63.5kg	Same

Table 2. Differences between Aperio GT 450 DX and the Predicate Device

Item	Predicate Device	Subject Device	Note
Product Name	Aperio GT 450 DX	Aperio GT 450 DX	-
510(k) No.	K232202	K253554	-
Z-Stacking Feature	No	Yes	Different. New function in the subject device.
Auto Narrow Stripe Feature	No	Yes	Different New function in the subject device.
Extended Focus Feature	No	Yes	Different New function in the subject device.
Manual Scan Feature	No	Yes	Different New function in the subject device.
20x Imaging	No	Yes	Different New function in the subject device.
Interoperable Display (Monitor)	DELL UP3017 Dell U3023E Dell U3223QE Barco MDPC-8127	DELL UP3017 Dell U3023E Dell U3223QE Barco MDPC-8127 +PCCP	Different LBS seeks clearance of the display qualification PCCP in the Aperio GT 450 DX modification 510(k).
Aperio WebViewer - interoperable File Format	SVS	SVS and DICOM	Different. Aperio WebViewer DX (Version 1.2) can read DICOM images by leveraging LVS service.
Viewer – Image Compression type	Lossy	Lossy and Lossless	Different. The LVS service can be configured to transfer tiles to the browser with lossless compression.

The modified Aperio GT 450 DX and the predicate device have the same Indications for Use, Intended Users, and Principle of Operation. There are no changes between the predicate device and the subject device in:

- Hardware
- Optical path
- Critical components

- Interoperability with the viewing software

The subject device includes only software modifications when compared to the predicate device.

Table 3. Similarities between Aperio GT 180 DX and the Predicate Device

Item	Predicate Device	Subject Device	Note
Item	**Predicate Device**	**Subject Device**	**Note**
Product Name	Aperio GT 450 DX	Aperio GT 180 DX	-
510(k) No.	K232202	K253554	-
Manufacturer	Leica Biosystems Imaging, Inc.	Leica Biosystems Imaging, Inc.	Same
Device Photo			-
Classification Regulation	21 CFR 864.3700	21 CFR 864.3700	Same
Product Code	PSY – Whole Slide Imaging System	PSY – Whole Slide Imaging System	Same
Classification Panel	(88) Pathology	(88) Pathology	Same
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,	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	Similar Added PCCP Added DICOM in Aperio WebViewer DX

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Table 1: Interoperable components of 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</td>
<td>The Aperio GT 180 DX is a WSI system. The technician places the slides into the Aperio GT 180 DX scanner. The Aperio GT 180 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</td>
<td>Same</td>
</tr>
</table>

	images acquired with the WSI scanner from the image storage, performs further QC, and reads WSI images of the slides to make a diagnosis.	acquired with the WSI scanner from the image storage, performs further QC, and reads WSI images of the slides to make a diagnosis.	
Prescription Use	Prescription Use Only	Prescription Use Only	Same
Use Environment	Clinical laboratory	Clinical laboratory	Same
Specimen Type	Formalin-Fixed Paraffin-Embedded (FFPE) Specimen	Formalin-Fixed Paraffin-Embedded (FFPE) Specimen	Same
Tissue Finding	Automatic	Automatic, manual	Same
Focusing System	Automatic	Automatic , manual	Same
Supported slide size	1 x 3 inch	1 x 3 inch	Same
Slide Loading Method	Automatic and Manual	Automatic and Manual	Same
Continuous Loading	Yes	Yes	Same
Scanning Magnification	40x	40x	Same
Scanning Resolution at 40x	0.26 µm/pixel	0.26 µm/pixel	Same
Scanning Region	≤ 23.6 mm x 58 mm for 1x 3 inch slide	≤ 23.6 mm x 58 mm for 1x 3 inch slide	Same
Scan Output Image Format	.svs and DICOM	.svs and DICOM	Same
Auto QC During Scanning	Yes	Yes	Same
Focusing Resolution at 40x	+/- 0.125 micron	+/- 0.125 micron	Same
Focusing error at 40x	+/- 0.5 micron	+/- 0.5 micron	Same
Focusing method	Real-Time focus and point focus	Real-Time focus and point focus	Same
Objective lens	40x/0.65 Plan Apo wide field	40x/0.65 Plan Apo wide field	Same
Color Reproducibility	Max ΔE< 10	Max ΔE< 10	Same
Image Storage	Images are stored in the end-user-provided image storage attached to the local network.	Images are stored in an end user-provided image storage attached to the local network.	Same
Throughput (includes slide handling) at 40x	81 slides per hour	81 slides per hour	Same
Turnaround Time	Within 3 seconds until the image is fully loaded.	Within 3 seconds until the image is fully loaded.	Same because the Viewer

			remains unchanged.
Image Manipulation Functions	Panning, zooming, gamma function, annotations, and measurements (distance)	Panning, zooming, gamma function, annotations, and measurements (distance)	Same because the Viewer remains unchanged.
Type of viewer Software Application	Web-based application	Web-based application	Same because the Viewer remains unchanged.
Interoperable Viewers	Aperio WebViewer DX Sectra Digital Pathology Module (3.3)	Aperio WebViewer DX Sectra Digital Pathology Module (3.3)	Same

Table 4. Differences between Aperio GT 180 DX and the Predicate Device

Item	Predicate Device	Subject Device	Note
Product Name	Aperio GT 450 DX	Aperio GT 180 DX	-
510(k) No.	K232202	K253554	-
Slide Storage/loading Capacity	450 slides, 1x 3 inch slide	180 slides, 1x 3 inch slide	Different. The subject device holds 60% less slides.
Rack carousel divider	15	6	Different. Aperio GT 180 DX has 60% less dividers based on the size of the carousel
Weight of the device	63.5kg	59kg	Different. Aperio GT 180 DX weighs less than Aperio GT 450 DX (4.5kg less).
Belt length and composition	1151mm	889mm	Different. Aperio GT 180 DX has a smaller diameter carousel than Aperio GT 450 DX.
LED Status Indicators in the Light Curtain	6	3	Different. Aperio GT 180 DX has 50% less LED status indicators, based on the smaller size of the carousel.
Number of Infrared Transmitters in Light Curtain	15	13	Different. Aperio GT 180 DX has fewer infrared transmitters (14% less).
Dimension (with cover assembled)	712 (Depth) * 530 (Width) * 495mm (Height)	650 (Depth) * 530 (Width) * 495mm (Height)	Different. The baseplate of Aperio GT 180 DX is shorter due to the smaller carousel. The width and height are the same as

			Aperio GT 450 DX.
Interoperable Display (Monitor)	DELL UP3017 Dell U3023E Dell U3223QE Barco MDPC-8127	DELL UP3017 Dell U3023E Dell U3223QE Barco MDPC-8127 +PCCP	Different LBS seeks clearance of the display qualification PCCP in the Aperio GT 450 DX modification 510(k).

The Aperio GT 180 DX and the predicate device have the same Indications for Use, Intended Users, and Principle of Operation.
There are no changes between the predicate device and the subject device in:

- Hardware
- Optical path
- Interoperability with the viewing software

The Aperio GT 180 DX is designed based on the Aperio GT 450 DX but is smaller and has a lower capacity. It features a 6-slot carousel that can hold up to 180 slides, while the Aperio GT 450 DX has a 15-slot carousel and can hold up to 450 slides. The Aperio GT 180 DX has a smaller diameter while maintaining the same height as the Aperio GT 450 DX. The Aperio GT 180 DX base plate's depth has been reduced, and the scanner display is now positioned closer to the back panel to accommodate the smaller diameter of the carousel. The graphical user interface (GUI) on the scanner displays 6 slots, corresponding to the 6-slot carousel, while the Aperio GT 450 DX has a GUI with 15 slots to match its 15-slot carousel. Additionally, the industrial design of the Aperio GT 180 DX scanner cover has been redesigned accordingly.

VI. Performance Data

I. Technical Studies

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

1) **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).

2) **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 Platform scanners.

3) **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.

4) **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.

5) **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 the slides' optical signals into 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.

6) **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.

7) **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.

8) **Image file format**

Information and specifications on the compression method, compression ratio, file format, and file organization were provided.

9) **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.

10) **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

11) **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.

12) **Color reproducibility**

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

13) **Spatial resolution**

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

14) **Focusing test**

Test data to evaluate the technical focus quality of the system was provided.

15) **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.

16) **Stitching error**

Test data to evaluate the stitching errors and artifacts in the reconstructed image was provided.

17) **Turnaround time**

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

18) **Pixel-Wise Comparison Study**

The pixelwise comparison study was conducted 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, 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.

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)].

II. User Interface/Human Factors Validation

Human factors studies were conducted for both Aperio GT 450 DX and Aperio GT 180 DX. The studies were designed around critical user tasks and use scenarios performed by representative histotechnicians. Eight of the histotechnicians tested with the Aperio GT 450 DX system, and eight histotechnicians tested with the Aperio GT 180 DX. All 16 histotechnicians tested Aperio SAM DX software.

The study's information included a list of all critical user tasks and a description of the followed process to identify them. A systematic evaluation was conducted, involving simulated use by representative users performing all tasks (including critical tasks) required for device operation, along with a subjective assessment of failure.

Out of the 16 critical tasks executed, 14 tasks were successfully completed by all users. This indicates that most users were able to safely execute critical tasks following training sessions on the new systems. Only two critical tasks did not generate a result of 'Passed' or 'Resolved' for all users. The Assisted and Unresolved results for those tasks do not indicate a safety failure requiring updates to the system. A software defect has been resolved, and no residual risks remain for critical tasks.

The learnability and ease of use were considerably high. All difficulties observed had a minimal impact on the perception of usability, and no difficulties or failures were observed in tasks that could have led to patient harm. In all instances, the histotechnicians were able to identify cases easily and ensure that everything was complete.

III. Aperio GT 450 DX Electromagnetic Compatibility (EMC) Testing

The Aperio GT 450 DX scanner meets the technical requirements of IEC/EN 61010-1:2010/AMD1: 2016, *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements* and 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.*

The Aperio GT 450 DX scanner meets the technical requirements of IEC/EN 61326-2-6:2013 *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment,* and the EMC Immunity requirements in the FDA Guidance, *Electromagnetic Compatibility (EMC) of Medical Devices* (June 6, 2022). It is important to note that in accordance with the FDA Guidance Document on EMC, and the FDA's partial recognition of the IEC 61326 series of EMC immunity standards as a consensus standard, a subset of higher EMC immunity test level (including Electrostatic discharge (ESD), Radio frequency interference (RFI), Electrical Fast Transient (EFT), Conducted RFI, and magnetic field) provided in IEC 60601-1-2:2014+A1:2020, *Amendment 1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests,* have been deemed appropriate and were applied during the course of this testing.

IV. Aperio GT 180 DX Electromagnetic Compatibility (EMC) Testing

The Aperio GT 180 DX scanner meets the technical requirements of IEC/EN 61010-1:2010/AMD1: 2016, Safety requirements for electrical equipment for measurement, control,

and laboratory use - Part 1: General requirements and 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.

The Aperio GT 180 DX scanner meets the technical requirements of IEC/EN 61326-2-6:2021 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment, and the EMC Immunity requirements in the FDA Guidance, Electromagnetic Compatibility (EMC) of Medical Devices (June 6, 2022). It is important to note that in accordance with the FDA Guidance Document on EMC, and the FDA's partial recognition of the IEC 61326 series of EMC immunity standards as a consensus standard, a subset of higher EMC immunity test level (including "Electrostatic discharge immunity test", "Radiated, radio-frequency, electromagnetic field immunity test", "Electrical fast transient/burst immunity test", "Surge immunity test", "Immunity to conducted disturbances, induced by radio-frequency fields", "Power frequency magnetic field immunity test" and "Voltage dips, short interruptions and voltage variations immunity tests") provided in IEC 60601-1-2:2014+A1:2020, Amendment 1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, have been deemed appropriate and were applied during the course of this testing.

V. Conclusions

The study results demonstrate that the Aperio GT 450 DX Modification is substantially equivalent to the predicate device, Aperio GT 450 DX, cleared under K232202.

The testing results demonstrate that Aperio GT 180 DX is substantially equivalent to the predicate device, Aperio GT 450 DX, cleared under K232202.