



November 25, 2025

Indica Labs, LLC
Michele Fredrickson
Director, Quality & Regulatory Affairs
8700 Education Pl NW, Building B
Albuquerque, NM 87114

Re: K252762

Trade/Device Name: HALO AP Dx
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Class: Class II
Product Code: QKQ
Dated: August 25, 2025
Received: August 29, 2025

Dear Michele Fredrickson:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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

Indications for Use

510(k) Number (if known)
K252762

Device Name
HALO AP Dx

Indications for Use (Describe)

HALO AP Dx is a software only device intended as an aid to the pathologist to review, interpret and manage digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue for the purposes of pathology primary diagnosis. HALO AP 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 quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. HALO AP Dx is intended for use with the interoperable components specified in the Table below.

Table: Interoperable Components of HALO AP Dx

Scanner Hardware	Scanner Output File Format	Interoperable Displays
Leica Aperio GT 450 DX scanner	SVS	Dell U3223QE Barco MDPC-8127
	DICOM	Dell U3223QE
Hamamatsu NanoZoomer S360MD Slide scanner	NDPI	Barco MDPC-8127

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

HALO AP Dx

Date Prepared: November 24, 2025

Submitter

Indica Labs, LLC
8700 Education Place NW, Building B
Albuquerque, NM, 87114 USA

Contact Person

Michele Fredrickson, Director Quality & Regulatory
Tel: 505-492-0972

Device

Proprietary/Trade Name: HALO AP Dx
Version Number: 2.4
Regulation Name: Whole Slide Imaging System
Regulation: 21 CFR §864.3700
Regulatory Class: Class II
Product Classification Code: QKQ
Review Panel: 88 – Pathology
510 (k) Submission Number: K252762

Predicate Devices

Predicate Manufacturer: Hamamatsu Photonics K.K.
Predicate Trade Name: NanoZoomer S360MD Slide scanner system
Predicate 510(k): K233027

Predicate Manufacturer: Leica Biosystems Imaging, Inc.
Predicate Trade Name: Aperio GT 450 DX
Predicate 510(k): K232202

No reference devices were used in this submission.

Intended Use

HALO AP Dx is a software only device intended as an aid to the pathologist to review, interpret and manage digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue for the purposes of pathology primary diagnosis. HALO AP Dx is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens.

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Device Description

HALO AP Dx, version 2.4 (abbreviated as v2.4), is a browser-based software-only device intended to aid pathology professionals in viewing, manipulating, management, and interpretation of digital pathology whole slide images (WSI) of glass slides obtained from the Hamamatsu Photonics K.K. NanoZoomer S360MD scanner or the Leica Biosystems Imaging, Inc. Aperio GT 450 DX.

HALO AP Dx is typically operated as follows:

1. Image acquisition is performed using the predicate device. The operator performs quality control of the digital slides per the instructions of the predicate device and lab specifications to determine if re-scans are necessary.
2. Once image acquisition is complete, according to its Instructions for Use, the unaltered image is saved in an external image storage location. HALO AP Dx ingests the image, and a copy of image metadata is stored in the subject device's database to improve viewing response times.
3. Depending upon a laboratory's workflow, the scanned images may first be reviewed by histotechnicians to confirm image quality and initiate any re-scans. After review, the histotechnician may modify the case status and make it available to the pathologist.
4. The reading pathologist selects a patient case from a selected worklist within HALO AP Dx whereby the subject device fetches the associated images from external image storage.
5. The reading pathologist uses the subject device to view the images and can perform the following actions, as needed:
 - a. Zoom and pan the image.
 - b. Measure distances and areas in the image.
 - c. Annotate images.
 - d. View multiple images side by side in a synchronized fashion.
6. The above steps are repeated as necessary.

After viewing all images belonging to a particular case (patient), the pathologist will make a diagnosis which is documented in another system, such as a Laboratory Information System.

HALO AP Dx operates and is validated for use with the FDA cleared components listed in the intended use statement table above.

Table 1: Computer Environment / System for Use with HALO AP Dx

Component	Requirement
Operating System	Windows 11
Memory	16 GB or more
Processor	Intel Core i7 CPU
Supported Browsers	Google Chrome version 138 or higher Microsoft Edge version 138 or higher

Table 2: Server System Requirements

Server	Operating System	Memory	Processor
Component Server, Processing Node Server, File Monitor Server	Windows Server 2022 Only x64 (64 bit) operating systems are supported	16 GB or more	8 CPU cores or more
Traefik Reverse Proxy	Windows Server 2022 Ubuntu 22.04	2GB, per 150 concurrent users	2 CPU Cores, per 150 concurrent users
MySQL Server	Windows Server 2022 Ubuntu 22.04 Only x64 (64 bit) operating systems are supported	16 GB or more	4 CPU Cores or more

Table 3: Server Configurations

Component	Specifications
Network Connectivity	1 Gbps (10 Gbps recommended) LAN connection between services
Antivirus Software	The following antivirus software has been validated for use with Windows Server: <ul style="list-style-type: none"> - Microsoft Windows Defender - Trend Micro - Webroot

Summary of Technological Characteristics

Comparison with Predicate – Hamamatsu NanoZoomer S360MD Slide scanner system

Item	Predicate (K233027)	Subject Device (K252762)									
Device Trade Name	Hamamatsu NanoZoomer S360MD Slide scanner system	HALO AP Dx									
Indications for Use	<p>The NanoZoomer S360MD Slide scanner system (“NanoZoomer System”) is an automated digital slide creation, viewing, and management system. The NanoZoomer System is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded (“FFPE”) tissue. The NanoZoomer System is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens.</p> <p>The NanoZoomer System comprises the NanoZoomer S360MD Slide scanner, the NZViewMD Software and a compatible display that has been 510(k) cleared for use with the NanoZoomer system or a 510(k)-cleared display that has been assessed in accordance with the Predetermined Change Control Plan (PCCP) for qualifying additional compatible displays. The NanoZoomer System is for creation and viewing of digital images of scanned glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using NanoZoomer System.</p>	<p>HALO AP Dx is a software only device intended as an aid to the pathologist to review, interpret and manage digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue for the purposes of pathology primary diagnosis. HALO AP Dx is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens.</p> <p>It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. HALO AP Dx is intended for use with the interoperable components specified in the Table below.</p> <p>Table: Interoperable Components of HALO AP Dx</p> <table border="1" data-bbox="889 1270 1469 1577"> <thead> <tr> <th data-bbox="889 1270 1089 1381">Scanner Hardware</th> <th data-bbox="1089 1270 1230 1381">Scanner Output File Format</th> <th data-bbox="1230 1270 1469 1381">Interoperable Displays</th> </tr> </thead> <tbody> <tr> <td data-bbox="889 1381 1089 1465">Leica Aperio GT 450 DX scanner</td> <td data-bbox="1089 1381 1230 1465">SVS</td> <td data-bbox="1230 1381 1469 1465">Dell U3223QE Barco MDPC-8127</td> </tr> <tr> <td data-bbox="889 1465 1089 1577">Hamamatsu NanoZoomer S360MD Slide scanner</td> <td data-bbox="1089 1465 1230 1577">DICOM</td> <td data-bbox="1230 1465 1469 1577">Dell U3223QE Barco MDPC-8127</td> </tr> </tbody> </table>	Scanner Hardware	Scanner Output File Format	Interoperable Displays	Leica Aperio GT 450 DX scanner	SVS	Dell U3223QE Barco MDPC-8127	Hamamatsu NanoZoomer S360MD Slide scanner	DICOM	Dell U3223QE Barco MDPC-8127
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Specimen Type	Surgical pathology slides prepared from FFPE tissue	Same									

Item	Predicate (K233027)	Subject Device (K252762)
Diagnostic Image File Format	Hamamatsu NDPI File	SVS and DICOM – Aperio GT 450 DX NDPI – Hamamatsu NanoZoomer S360MD Slide scanner system
Image Manipulation and Review Functions	Functions for continuous panning and zooming, annotations, distance/area measurements, track visited areas, and image adjustments.	Same
Type of Software Application	PC-based installed application	Internet browser-based application
Principle of Operation	During review, the pathologist opens the WSI images acquired with the scanner from the network storage, performs further QC, and reviews and interprets the WSI images to make a diagnosis.	Same
Image Storage	User-supplied network attached storage	Same
End User's Interface	NZViewMD	HALO AP Dx
Scanner	Hamamatsu NanoZoomer S360MD	Aperio GT 450 DX Hamamatsu Nanozoomer S360MD

Comparison with Predicate – Aperio GT 450 DX

Item	Predicate (K232202)	Subject Device (K252762)
Device Trade Name	Aperio GT 450 DX	HALO AP Dx
Indications for Use	<p>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</p> <p>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</p> <p>images of scanned glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy.</p>	<p>HALO AP Dx is a software only device intended as an aid to the pathologist to review, interpret and manage digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue for the purposes of pathology primary diagnosis. HALO AP Dx is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens.</p> <p>It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the</p>

Item	Predicate (K232202)	Subject Device (K252762)																											
	<p>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.</p> <p>Table 1: Interoperable components of Aperio GT 450 DX</p> <table border="1" data-bbox="298 730 919 1255"> <thead> <tr> <th>Scanner Hardware</th> <th>Scanner Output File Format</th> <th>Interoperable Viewing Software</th> <th>Interoperable Displays</th> </tr> </thead> <tbody> <tr> <td>Leica 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>Leica Aperio GT 450 DX scanner</td> <td>SVS</td> <td>Sectra Digital Pathology Module (3.3)</td> <td>Dell U3223QE</td> </tr> <tr> <td>Leica Aperio GT 450 DX scanner</td> <td>DICOM</td> <td>Sectra Digital Pathology Module (3.3)</td> <td>Dell U3223QE</td> </tr> </tbody> </table> <p>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.</p>	Scanner Hardware	Scanner Output File Format	Interoperable Viewing Software	Interoperable Displays	Leica Aperio GT 450 DX scanner	SVS	Aperio WebViewer DX	Barco MDPC-8127 Dell UP3017 Dell U3023E Dell U3223QE	Leica Aperio GT 450 DX scanner	SVS	Sectra Digital Pathology Module (3.3)	Dell U3223QE	Leica Aperio GT 450 DX scanner	DICOM	Sectra Digital Pathology Module (3.3)	Dell U3223QE	<p>quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. HALO AP Dx is intended for use with the interoperable components specified in the Table below.</p> <p>Table: Interoperable Components of HALO AP Dx</p> <table border="1" data-bbox="937 573 1502 905"> <thead> <tr> <th>Scanner Hardware</th> <th>Scanner Output File Format</th> <th>Interoperable Displays</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Leica Aperio GT 450 DX scanner</td> <td>SVS</td> <td>Dell U3223QE Barco MDPC-8127</td> </tr> <tr> <td>DICOM</td> <td>Dell U3223QE</td> </tr> <tr> <td>Hamamatsu NanoZoomer S360MD Slide scanner</td> <td>NDPI</td> <td>Barco MDPC-8127</td> </tr> </tbody> </table>	Scanner Hardware	Scanner Output File Format	Interoperable Displays	Leica Aperio GT 450 DX scanner	SVS	Dell U3223QE Barco MDPC-8127	DICOM	Dell U3223QE	Hamamatsu NanoZoomer S360MD Slide scanner	NDPI	Barco MDPC-8127
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Item	Predicate (K232202)	Subject Device (K252762)
Review Functions	measurements, track visited areas, and image adjustments.	
Type of Software Application	Internet browser-based application	Same
Principle of Operation	During review, the pathologist opens the WSI images acquired with the scanner from the network storage, performs further QC, and reviews and interprets the WSI images to make a diagnosis.	Same
Image Storage	User-supplied network attached storage	Same
End User's Interface	WebViewer DX for Leica SVS, Sectra Digital Pathology Module (3.3) for Leica SVS and DICOM	HALO AP Dx
Scanner	Aperio GT 450 DX	Aperio GT 450 DX NanoZoomer S360MD Slide scanner

Summary of Studies (Performance Data)

Performance Data	Description																										
Identical image reproduction	Pixel-level comparisons were made to compare images displayed by HALO AP Dx (v2.4) and the predicate devices' image review and manipulation software (IRMS) as described below for the same scanned image file format as captured from the same FDA cleared scanning system to validate identical image display on the same compatible display monitors.																										
	<table border="1"> <thead> <tr> <th>Scanning System</th> <th>File Format</th> <th>Predicate Device IRMS</th> <th>Subject Device</th> <th>Display</th> </tr> </thead> <tbody> <tr> <td rowspan="4">Aperio GT 450 DX</td> <td rowspan="2">SVS</td> <td>WebViewer DX (Google Chrome)</td> <td>HALO AP Dx (Google Chrome)</td> <td>Barco MDPC-8127</td> </tr> <tr> <td>WebViewer DX (Microsoft Edge)</td> <td>HALO AP Dx (Microsoft Edge)</td> <td>Dell U3223QE</td> </tr> <tr> <td rowspan="2">DICOM</td> <td>Sectra Digital Pathology Module (IDS7)</td> <td>HALO AP Dx (Google Chrome)</td> <td rowspan="2">Dell U3223QE</td> </tr> <tr> <td>Sectra Digital Pathology Module (IDS7)</td> <td>HALO AP Dx (Microsoft Edge)</td> </tr> <tr> <td rowspan="2">Hamamatsu NanoZoomer S360MD Slide scanner</td> <td rowspan="2">NDPI</td> <td>NZViewMD</td> <td>HALO AP Dx (Google Chrome)</td> <td rowspan="2">Barco MDPC-8127</td> </tr> <tr> <td>NZViewMD</td> <td>HALO AP Dx (Microsoft Edge)</td> </tr> </tbody> </table>	Scanning System	File Format	Predicate Device IRMS	Subject Device	Display	Aperio GT 450 DX	SVS	WebViewer DX (Google Chrome)	HALO AP Dx (Google Chrome)	Barco MDPC-8127	WebViewer DX (Microsoft Edge)	HALO AP Dx (Microsoft Edge)	Dell U3223QE	DICOM	Sectra Digital Pathology Module (IDS7)	HALO AP Dx (Google Chrome)	Dell U3223QE	Sectra Digital Pathology Module (IDS7)	HALO AP Dx (Microsoft Edge)	Hamamatsu NanoZoomer S360MD Slide scanner	NDPI	NZViewMD	HALO AP Dx (Google Chrome)	Barco MDPC-8127	NZViewMD	HALO AP Dx (Microsoft Edge)
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	<p>Thirty (30) formalin-fixed paraffin-embedded (FFPE) slides representing a range of anatomical sites and diagnoses were scanned on the predicate scanning systems at 40x magnification. Three ROIs were identified per slide and captured at two magnification levels (10x and 40x) across each viewer, browser (if applicable), and display combination. Each predicate IRMS and subject device ROI was registered and the difference between each pixel was computed using the 2000 International Commission on Illumination color difference CIEDE2000 metric (ΔE_{00}). The 95th percentile of the pixelwise ΔE_{00} differences for each ROI in the compared image sets was reported. An acceptance criterion where each analyzed ROI image pair shall not have a 95th percentile of the pixelwise ΔE_{00} differences value greater than 3 was applied.</p> <p>The final test results showed that 95th percentile of the pixelwise ΔE_{00} differences for each ROI was less than 3 for all compared image sets. Therefore, HALO AP Dx and the predicate IRMS image display has been found to be pixelwise equivalent.</p>
Turnaround time	<p>Turnaround times for image loading, panning, and zooming have been determined and found to be adequate for the intended use of the subject device. The system requirements have been fulfilled:</p> <ul style="list-style-type: none"> • When selecting a case, it should not take longer than 4 seconds until the image is fully loaded. • When panning the image, it should not take longer than 3 seconds until the image is fully loaded.
Measurements	<p>Measurement accuracy has been verified using a test image containing objects with known sizes.</p>
Human factors testing	<p>A human factors study was conducted per FDA's Guidance on Applying Human Factors and Usability Engineering to Medical Devices (2016). The study was designed around critical and essential user tasks and use scenarios performed by representative users was conducted for previously cleared HALO AP Dx (version 2.1) in K232833. No new human factors study was performed for HALO AP Dx (version 2.4).</p>

Substantial Equivalence Comparison

The proposed subject device has similar Indications for Use, principles of operation, and technical characteristics as compared to each predicate device's IRMS. Performance testing results confirm equivalent image reproducibility, measurement accuracy, and similar or better turnaround times for common operations. Therefore, the subject device is confirmed to be substantially equivalent to the predicate devices.

Conclusion

Based on the information provided, when HALO AP Dx is used with the Hamamatsu Photonics K.K. NanoZoomer S360MD Slide scanner or Leica Biosystems Imaging, Inc. Aperio GT 450 DX and the interoperable monitor displays, it has similar Indications for Use, Functional, and Technological Characteristics as the applicable predicate IRMS. The performance data support substantial equivalence of HALO AP Dx to the predicate devices.