Proscia, Inc.
Ian Cadieux
Head of Quality and Regulatory
1700 Market St.
Floor 24
Philadelphia, PA 19103

August 5, 2026

Re: K261380
Trade/Device Name: Concentriq AP-Dx
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: QKQ
Dated: April 27, 2026
Received: April 27, 2026

Dear Ian Cadieux:

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.

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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)*
K261380

Device Name
Concentriq AP-Dx

Indications for Use *(Describe)*
Concentriq AP-Dx is a software only device intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret and manage these digital slide images for the purpose of pathology primary diagnosis. Concentriq AP-Dx is not intended for use with frozen sections, 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 the validity of the interpretation of images using Concentriq AP-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

Concentriq® AP-Dx

Date Prepared July 15, 2026

Submitter / Contact Information

Applicant	Proscia, Inc. 1700 Market Street Floor 24 Philadelphia, PA 19103
Contact Person	Ian Cadieux Head of Quality and Regulatory
Contact Phone	619-894-0873
Contact Email	ian.cadieux@proscia.com

Device

Device Trade Name	Concentriq AP-Dx
Common Name	Whole slide imaging system
Classification Name	Digital Pathology Image Viewing and Management Software
Regulation Number	864.3700
Product Code(s)	QKQ
Submission Number	K261380

Predicate Device(s)

510(k) Number	Predicate Trade Name	Product Code
K232202	Aperio GT 450 DX	PSY
K230839	Concentriq Dx	QKQ

Purpose for Submission

- Addition of Leica Aperio GT 450 DX (SVS format) as an interoperable component to Concentriq AP-Dx.
- Addition of NanoZoomer S540MD Slide scanner system as an interoperable component to Concentriq AP-Dx.
- Addition of Dell U3223QE display as an interoperable component to Concentriq AP-Dx.
- Transition to a cloud deployment architecture, with no change to core clinical functionality.
- Establish a Pre-Determined Change Control Plan (PCCP) for qualifying and adding additional FDA-cleared whole slide image scanners and displays as interoperable components to Concentriq AP-Dx.

Intended Use / Indications for Use

Concentriq AP-Dx is a software only device intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret and manage these digital slide images for the purpose of pathology primary diagnosis. Concentriq AP-Dx is not intended for use with frozen sections, 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 the validity of the interpretation of images using Concentriq AP-Dx.

Device Description

Concentriq AP-Dx is a web-based, software-only device that is intended to aid pathology professionals in viewing, interpretation, and management of digital whole slide images of scanned surgical pathology slides prepared from formalin-fixed, paraffin-embedded (FFPE) tissue obtained from validated whole slide imaging scanners. It aids the pathologist in the review, interpretation, and management of pathology slide digital images used to generate a primary diagnosis.

Concentriq AP-Dx is operated as follows:

1. The image acquisition is performed using the validated WSI scanner. A lab technician prepares, and scans slides and reviews the slide quality in accordance with the WSI scanner Instruction Manual and standard lab procedures. Concentriq AP-Dx workflow is initiated when the whole slide image from the local file system is ingested into Concentriq AP-Dx.

2. The reading pathologist selects a case from a worklist external to the subject device or from within the subject device, whereby the subject device fetches the associated images from the image storage.

3. The reading pathologist uses the subject device to view and interpret the images:

Zoom and pan the image

Measure distances and areas in the image

Annotate the image

View multiple images side by side

4. Prior to using a whole slide image for diagnosis, a data and image quality assessment is performed.

5. The above steps are repeated as required.

6. After viewing all images for a case, the pathologist will make a diagnosis. The diagnosis will be documented in another system, e.g., Laboratory Information System (LIS).

Concentriq AP-Dx is validated and intended to be used with specified interoperable components as defined in Table 1 or a 510(k) cleared whole slide imaging scanner or a 510(k) cleared display that has been assessed in accordance with the Predetermined Change Control Plan (PCCP).

System requirements are provided in Table 2.

Table 1: Interoperable WSI components

Scanner	Scanned File Type	Monitor
Leica Aperio GT 450 DX	.SVS	Dell U3223QE JVC JD-C24BN01A
Hamamatsu NanoZoomer S360MD	.NDPI	

Table 2: Minimum System Requirements

Workstation Component	Specifications
Processor	2 GHz processor or higher with at least 4 cores
Memory	16 GB RAM must be available for use by Concentriq
Network connectivity	100 Mbps. (1 Gbps LAN recommended) connection
Operating system	Windows 11
Supported browsers	Google Chrome 142 and above, Microsoft

	Edge 142 and above
Optional input devices	3Dconnexion SpaceMouse® Pro 3Dconnexion SpaceMouse® Compact

Pre-determined Change Control Plan (PCCP)

A PCCP will be followed to validate the interoperability of additional FDA-cleared slide scanners and displays with Concentriq AP-Dx including specific performance requirements that must be met prior to updating the device labeling to reference the newly added slide scanners or displays. With inclusion of the PCCP, future changes to add additional FDA-cleared scanners and displays to the labeling can be made in accordance with the PCCP without a premarket submission. The Proscia Inc. website will provide information on additional slide scanners and displays that are interoperable with Concentriq AP-Dx and allow users to request updated versions of the software labeling.

Predicate Comparison Table

Table 3: Predicate Comparison

<table>
<tr><th>Spec.</th><th>Predicate Device (K232202)</th><th>Predicate Device (K230839)</th><th>Subject Device (K261380)</th></tr>
<tr><td>Device Trade Name</td><td>Aperio GT 450 DX</td><td>Concentriq Dx</td><td>Concentriq AP-Dx</td></tr>
<tr><td>Product Code</td><td>PSY</td><td>PSY, QKQ</td><td>QKQ</td></tr>
<tr><td>Regulation</td><td>21 CFR 864.3700</td><td>21 CFR 864.3700</td><td>21 CFR 864.3700</td></tr>
<tr><td>Regulation Name</td><td>Whole Slide Imaging System</td><td>Whole Slide Imaging System</td><td>Whole Slide Imaging System (Digital pathology image viewing and management software)</td></tr>
<tr><td>Classification</td><td>II</td><td>II</td><td>II</td></tr>
<tr><td colspan="4">General Device Characteristics - Similarities</td></tr>
<tr><td>Indications for 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 following interoperable components specified in Table 1.
<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 MDPC8127
Dell UP3017
Dell U3023E
Dell U3223QE</td></tr>
</table></td><td>Concentriq Dx is a software only device intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret and manage these digital slide images for the purpose of primary diagnosis. Concentriq® Dx is not intended for use with frozen sections, 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 the validity of the interpretation of images using Concentriq Dx.
Concentriq Dx is intended for use with the Hamamatsu NanoZoomer S360MD Slide scanner and JVC JD-C240BN01A monitor.</td><td>Concentriq AP-Dx is a software only device intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret and manage these digital slide images for the purpose of pathology primary diagnosis. Concentriq AP-Dx is not intended for use with frozen sections, 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 the validity of the interpretation of images using Concentriq AP-Dx.</td></tr>
</table>

Spec.	Predicate Device (K232202)	Predicate Device (K230839)	Subject Device (K261380)
	<table><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		
Scanner	Aperio Leica GT 450 DX	Hamamatsu NanoZoomer S360MD Slide scanner	Hamamatsu NanoZoomer S360MD Slide scanner, Aperio Leica GT 450 DX, or FDA-cleared scanning hardware validated per the PCCP to ensure performance requirements are met prior to modifications being implemented.
Compatible Display	BARCO MDPC-8127, Dell UP3017, Dell U3023E, Dell U3223QE	JVC JD-C240BN01A	JVC JD-C240BN01A, Dell U3223QE, or FDA-cleared display validated per the PCCP to ensure requirements are met prior to modifications being implemented.
Specimen Type	Surgical pathology slides prepared from FFPE tissue	Surgical pathology slides prepared from FFPE tissue	Surgical pathology slides prepared from FFPE tissue
Image File Format	SVS, DICOM	NDPI	NDPI, SVS, or formats FDA-cleared with scanning hardware validated per the PCCP to ensure performance requirements are met prior to modifications being implemented.
Image Viewing and Measurement Functions	Panning, zooming, gamma function, annotations, and measurements (distance)	Panning, zooming, image adjustments, annotations, and distance/area measurements	Panning, zooming, image adjustments, annotations, and distance/area measurements
Type of Software Application	Internet browser based	Internet browser based	Internet browser based

Spec.	Predicate Device (K232202)	Predicate Device (K230839)	Subject Device (K261380)
Principle of Operation	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.	After the WSI are acquired by using NanoZoomer S360MD Slide scanner, the WSI are stored in customer provided image storage. During image review, the pathologist opens the WSI (displayed as .ndpi images) from the image storage using Concentriq Dx; performs further QC and then reads the WSI to make a diagnosis.	After whole slide images are acquired by using a NanoZoomer S360MD Slide scanner, or Aperio GT450 DX, or other scanning hardware validated per the PCCP, the images are stored in customer provided image storage. Images are then ingested into Concentriq AP-Dx image storage. During image review, the pathologist opens the image from the image storage using Concentriq AP-Dx; performs further QC, and then reads the whole slide image to make a diagnosis.
General Device Characteristics – Differences			
Device Components	Scanner, Image Management Software and Display	Image Management Software	Image Management Software
User Interface	NZViewMD	Concentriq Dx	Concentriq AP-Dx

Substantial Equivalence: Indications for Use Comparison

The subject device is similar to the predicate, having similar indications for use, intended use and technological characteristics as its predicate devices, with the exception of the implementation of a PCCP that specifies the protocols and acceptance criteria for validating and adding additional FDA cleared scanners and file formats, and additional FDA cleared pathology displays as interoperable components to Concentriq AP-Dx in a controlled manner, such that the device is as safe and as effective as the predicate devices.

Substantial Equivalence: Technical Characteristics Comparison

Concentriq AP-Dx has the same technological characteristics as the predicate devices. The devices are, or include, web-browser based software for ingesting digital whole slide images and enabling image viewing and measurement functions including panning, zooming, image adjustments, annotations, and distance measurements. The viewing software is used as part of a whole slide imaging system additionally comprised of scanner hardware and 510(k)-cleared display.

Performance Data

Pixel-wise Comparison Testing:

Aperio GT 450 DX with Aperio WebViewer DX (K232202)

A pixel-wise comparison test was performed to compare SVS images reproduced by Concentriq AP-Dx for the same image generated by the reference device Leica Aperio GT 450 DX with the Aperio WebViewer DX to verify the images in Concentriq AP-Dx are identical. Two images are considered identical if the 95th percentile of the pixelwise differences, computed using the International Commission on Illumination (CIE) color difference metric CIEDE2000 (ΔE00), is less than 3 ΔE00.

For each of 30 FFPE WSIs (Whole Slide Images) included in the testing, three regions of interest (ROIs) at 40x and three ROIs at 20x were selected. For each ROI, the differences between the views generated by Concentriq AP-Dx and the reference device were evaluated using the International Commission on Illumination (CIE) color

difference metric CIEDE2000 (ΔE) for each corresponding pixel pair. The Image Integrity Evaluation System (IVIES) Medical Device Development Tool (MDDT) was used to calculate the pixelwise color difference using the CIEDE2000 (ΔE00) metric. Of the 180 ROIs evaluated, the 95th percentile pixelwise color differences range from 1.31 to 2.72 CIEDE2000. Testing was performed with Chrome and Edge browsers with identical results.

NanoZoomer S360MD with Concentriq Dx (K230839)

A pixel-wise comparison test was performed to compare images scanned by the NanoZoomer S360MD Slide scanner reproduced by Concentriq AP-Dx for the same image reproduced by the reference device Concentriq Dx (K230839) to verify the images in the latest version of Concentriq AP-Dx are identical to those of the clinically validated system. Two images are considered identical if the 95th percentile of the pixelwise differences, computed using the International Commission on Illumination (CIE) color difference metric CIEDE2000 (ΔE00), is less than 3 ΔE00.

For each of 30 FFPE WSIs (Whole Slide Images) included in the testing, three regions of interest (ROIs) at 40x and three ROIs at 20x were selected. For each ROI, the differences between the views generated by Concentriq AP-Dx and the reference device were evaluated using the International Commission on Illumination (CIE) color difference metric CIEDE2000 (ΔE) for each corresponding pixel pair. The Image Integrity Evaluation System (IVIES) Medical Device Development Tool (MDDT) was used to calculate the pixelwise color difference using the CIEDE2000 (ΔE00) metric. Of the 180 ROIs evaluated, the 95th percentile pixelwise color differences range from 0.70 to 1.66 CIEDE2000. Testing was performed with Chrome and Edge browsers with identical results.

Measurement Accuracy:

Measurement accuracy was verified by comparing the measurements of markings made in the Concentriq AP-Dx viewer to the measurements of markings on a calibrated slide with known dimensions. The test data showed that the distance and area measurements made in the Concentriq AP-Dx viewer were consistent with the ground truth. These results demonstrated acceptable measurement accuracy with respect to its intended use.

Table 4: Concentriq AP-Dx Measurement Results

Scanner	Image File Format	Subject Device/Browser	Percentage Error (%) Compared to Ground Truth	
			Length Measurement	Area Measurement
Leica Aperio GT 450 DX scanner	.SVS	Concentriq AP-Dx / Chrome	≤ 1%	≤ 1%
Hamamatsu NanoZoomer S360MD	.NDPI	Concentriq AP-Dx / Chrome	≤ 1%	≤ 1%

Turnaround Time:

The time to initially load an image and the time to load an image when panning and zooming while using Concentriq AP-Dx to view WSI images was measured. The testing included scenarios and image sizes representing anticipated regular use of Concentriq AP-Dx. The test execution demonstrated maximum turnaround times of less than 2 seconds across all scenarios.

Table 5: Concentriq AP-Dx Turnaround Time Testing Results

Scanner	Image File Format	Subject Device/Browser	Results (Seconds)		
			Loading and Display	Panning	Zooming
Leica Aperio GT 450 DX scanner	SVS	Concentriq AP-Dx / Chrome	Max = 0.389 Min = 0.242 Mean = 0.319	Max = 1.430 Min = 1.181 Mean = 1.208	Max = 1.218 Min = 1.181 Mean = 1.196

		Concentriq AP-Dx / Edge	Max = 0.617 Min = .248 Mean = .339	Max = 1.437 Min = 1.181 Mean = 1.208	Max = 1.217 Min = 1.181 Mean = 1.197

Human Factors Validation:

A human factors study was previously conducted on Concentriq Dx (K230839) to assess the use-related safety and effectiveness with representative users in a representative use environment to provide adequate evidence that the user interface design (including the device and labeling) supports safe and effective use.

The evaluation method followed the 2016 Food and Drug Administration Guidance titled "Applying Human Factors and Usability Engineering to Medical Devices". The device was found to be safe and effective for the intended users, uses and use environments. The results of the study are applicable to Concentriq AP-Dx. No new human factors study was performed for Concentriq AP-Dx.

Conclusion

Based on the information provided in the 510(k), the subject device Concentriq AP-Dx is substantially equivalent to the previously cleared predicate devices, when used with the Hamamatsu NanoZoomer S360MD or Leica Aperio GT 450 DX slide scanners and Dell U3223QE or JVC JD-C240BN01A monitors, or FDA-cleared displays and slide scanners validated and implemented per the authorized PCCP.