510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K261380

B Applicant

Proscia Inc.

C Proprietary and Established Names

Concentriq AP-Dx

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QKQ	II	21 CFR 864.3700	Pathology

II Submission/Device Overview:

A 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.

B Type of Test:

Software only device

III Intended Use/Indications for Use:

A Intended Use(s):

See Indication(s) for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

Concentriq AP-Dx (version 4.10) is a web-based, software-only device that is intended to aid pathology professionals in viewing, interpretation, and management of digital whole slide images (WSIs) of scanned surgical pathology slides prepared from FFPE tissue obtained from intended use interoperable scanners. It aids the pathologist in the review, interpretation, and management of pathology slide digital images used to generate a pathology primary diagnosis.

Concentriq AP-Dx is operated as below:

1. After the WSI image is acquired by the intended use slide scanner accordance to the WSI scanner Instructional Manual and any additional standard laboratory procedures, the WSI from the local file system is ingested into Concentriq AP-Dx at which point the Concentriq AP-Dx workflow is initiated.
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 image quality and other image data is evaluated and deemed acceptable, prior to using a whole slide image for diagnosis.
4. The reading pathologist uses the subject device to view and interpret the images using the following actions:
    - Zoom and pan the image
    - Measure distances in the image
    - Annotate the image
    - View multiple images side by side
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., a Laboratory Information System (LIS).

Concentriq AP-Dx is designed to be deployed to a cloud infrastructure and accessed through a web-browser (client) on user's workstation within a customer managed network.

Concentriq AP-Dx is intended to be used with the specified interoperable components as specified in Table 1. System requirements are listed in Table 2.

Table 1: Interoperable WSI components

Scanner	Scanned File Type	Monitor (Display)
Leica Aperio GT 450 DX	.SVS	Dell U3223QE JVC JD-C24BN01A
Hamamatsu NanoZoomer S360MD	.NDPI	
Additional FDA cleared scanners/file formats that have been assessed in accordance with the Predetermined Change Control Plan (PCCP) for qualifying additional interoperable scanners		Additional FDA cleared displays that have been assessed in accordance with the Predetermined Change Control Plan (PCCP) for qualifying additional interoperable displays

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

B Instrument Description Information:

1. Instrument Name:
   Concentriq AP-Dx

2. Specimen Identification:
   Concentriq AP-Dx utilizes WSIs acquired from Hematoxylin and Eosin (H&E) stained glass slides using the Leica Aperio GT 450 DX scanner or Hamamatsu NanoZoomer S360MD Slide scanner. A laboratory technician prepares and scans slides using the intended use

scanner to generate the WSIs. The Concentriq AP-Dx workflow is initiated when the WSI from the local file system is ingested into Concentriq AP-Dx where the reading pathologist selects a case (patient) for viewing with the subject device. The scanned images are identified using the specimen identifier previously assigned to the case.

3. Specimen Sampling and Handling:
   Specimen sampling and handling are performed upstream and independent of the use of the subject device. Specimen sampling includes biopsy or resection specimens which are processed using histology techniques. Digital images (WSIs) are then obtained from these glass slides using the intended use scanner.

4. Calibration:
   Not Applicable

5. Quality Control:
   WSIs are acquired using the intended use scanner according to its instructions for use and are uploaded to the Concentriq Dx storage and associated to case and slide metadata. Images are opened in the Concentriq Dx viewer and the following quality control activities are performed by the user:
   - Compare the slide macro image to the slide navigator and/or the image in the viewer to confirm all tissue on the slide has been scanned.
   - Confirm the information on the slide label of the image is accurate for the case, block, and slide.

   It is the responsibility of the pathologist to confirm that the case is complete and accurate and that the case has the expected number of images before completing review.

V Substantial Equivalence Information:

A Predicate Device Name(s):
1. Aperio GT 450 DX
2. Concentriq Dx

B Predicate 510(k) Number(s):
1. K232202
2. K230839

C Comparison with Predicate(s):

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 the Concentriq AP-Dx in a controlled manner, such that the device is as safe and as effective as the predicate devices. The description of the planned modifications, testing methods, validation activities, performance requirements, and communication to users are part of the device quality system and are summarized below.

Planned modifications by PCCP

a. Additional Scanners and File Formats:
To include additional FDA cleared scanners (candidate) and associated file formats, the candidate scanners will be verified and validated in accordance with the requirements outlined in the PCCP protocol. Additional FDA cleared file formats of the scanner will be verified and validated through pixel-wise comparison testing which should demonstrate that the new FDA-cleared scanner and associated file format produce images that are identical to those generated by the predicate device. Upon successful validation, the design change will be implemented according to the quality management system, and the new scanner and associated file formats may be added as an interoperable component to the Concentriq AP-Dx without additional premarket review. Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device's compatible scanner hardware.

b. Additional Displays:
To include additionally FDA-cleared displays, the candidate displays will be verified and validated in accordance with a system-level integration test which will be conducted to confirm that the new display functions adequately with the complete WSI system, including the original scanner and viewer components. If the candidate display meets the acceptance criteria specified in the PCCP, the design change will be implemented according to the quality management system and the new display may be added as an interoperable component to the subject device without additional premarket review. Following successful validation, the device labeling will be updated in accordance with the authorized PCCP to ensure that users are provided with accurate and current information regarding display interoperability. The device labeling and company website will be revised to identify the new display according to the quality management system.

The similarities and differences between the Concentriq AP-Dx and the predicate devices, Aperio GT 450 DX Concentriq Dx, are summarized in Table 3 below.

Table 3: Comparison with Predicates

Device & Predicate Device(s):	Subject Device K261380	Predicate Device K232202	Predicate Device K230839
Device Trade Name	Concentriq AP-Dx	Aperio GT 450 DX	Concentriq Dx
General Device Characteristic Similarities			
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	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	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

	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.	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: Scanner Hardware: Aperio GT 450 DX scanner; Scanner Output file format: SVS; Interoperable Viewing Software: Aperio WebViewer DX; Interoperable Displays: Barco MDPC8127, Dell UP3017, Dell U3023E, Dell U3223QE Scanner Hardware: Aperio GT 450 DX scanner; Scanner Output file format: SVS; Interoperable Viewing Software: Sectra Digital Pathology Module (3.3); Interoperable Displays: Dell U3223QE Scanner Hardware: Aperio GT 450 DX scanner; Scanner Output file format: DICOM; Interoperable Viewing Software: Sectra Digital Pathology Module (3.3); Interoperable Displays: Dell U3223QE 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.	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.

General Device Characteristic Differences			
Device Components	Image Management Software	Scanner, Image Management Software, Display	Image Management Software
User Interface	Concentriq AP-Dx	NZViewMD	Concentriq Dx

VI Standards/Guidance Documents Referenced:

1. For evaluation of risk and risk management the sponsor referred to ANSI AAMI ISO, 14971: 2019, Medical devices - Applications of risk management to medical devices.
2. For the human factors validation, the sponsor referenced the 2016 FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" and ANSI AAMI IEC, 62366-1:2015+AMD1:2020 (Consolidated Text), Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1.
3. For performance evaluation, the sponsor referred to the 2025 FDA guidance "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices, Guidance for Industry and Food and Drug Administration Staff" and CIE ISO 11664-6 First edition 2014-02-01.
4. For cybersecurity evaluation, the sponsor referred to the 2025 FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Guidance for Industry and Food and Drug Administration Staff".

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   Not applicable

2. Linearity:
   Not applicable

3. Analytical Specificity/Interference:
   Not applicable

4. Accuracy:
   Not applicable

B Other Supportive Instrument Performance Characteristics Data:

Technical performance testing was conducted with the subject device, Concentriq AP-Dx as specified below.

1. Pixel-wise Comparison Testing

Pixel-wise comparison testing was performed to support Aperio GT 450 DX and NanoZoomer S360MD Slide scanner as interoperable components to Concentriq AP-Dx.

Concentriq AP-Dx supports multiple file formats, multiple browsers, and multiple displays, constituting various configurations to be tested. Pixel-wise comparison testing to demonstrate identical image reproduction was conducted to compare WSIs reproduced by the subject device and the comparators as listed in Table 4 below. The subject device was compared to the predicate device's image review manipulation software (IRMS), as defined in FDA guidance document, "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices" dated April 20, 2016) using the quantitative pixel-wise comparison method. The basis for the comparison was the CIEDE2000 color difference equation, ΔE00. The devices were tested as operating with the intended components, including the scanner, specific file format, image management systems (subject device with the intended browsers, comparator [predicate device IRMS]) and displays, as specified in the Table 4 below.

For each of the 4 configurations in Table 4 below, the device was tested with multiple slides across multiple regions of interest (ROI) at multiple magnification levels, on multiple displays. A total of 30 H&E-stained, FFPE glass slides from various intended use tissue samples were used in the testing. For each configuration, the glass slides were scanned on a corresponding intended scanner to obtain 30 WSIs. For each of the 30 WSIs, 3 ROIs from different locations were selected by qualified personnel to represent various features in the tissue samples. Each ROI was captured at 2 magnification levels (20x, 40x).

The screenshots were captured for each of the intended display while viewing with the subject device and predicate device IRMS. The screenshots were cropped and registered to be pixelwise comparable. The cropped image included most of the pixels in the image except for those in the viewer-specific user interface areas.

For each configuration and each intended display, two sets of images were collected: comparator (predicate device IRMS) and the subject device (Concentriq AP-Dx with the intended browser). Each image set included 180 images that covered all combinations of 30 slides, 3 ROIs and 2 magnification levels. The testing data, including the overview images of the 30 glass slides with annotations of the ROIs, registration/cropping information, and captured images, were provided in the FDA specific format. The above procedure was repeated for each corresponding intended display.

The comparator (predicate device IRMS) image set was used as the reference to compare the subject device image set to determine whether all the 180 image-pairs were identical for each configuration and each intended display. 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.

The sponsor utilized the Image Integrity Evaluation System (IVIES) Medical Device Development Tool (MDDT) to calculate the pixelwise color difference using the CIEDE2000 (ΔE00) metric [Image Viewer Integrity Evaluation System (IVIES)].

Testing results showed that the pixelwise differences across all 180 image-pairs per configuration and per intended display were less than 3 ΔE00. The maximum (max), minimum (min), and mean of the 95th percentile ΔE00 value were reported. Testing

results demonstrated that WSIs reproduced by HALO AP Dx are identical to images reproduced by the predicate devices.

Table 4: Concentriq AP-Dx Pixelwise Comparison Testing Results

Scanner	Image File Format	Subject Device	Comparator (Predicate Device IRMS/Browser)	Display	Browser	Results of 95th percentile ΔE_{00} Maximum, Minimum, Mean
Aperio GT 450 Dx	SVS	Concentriq AP-Dx	Aperio WebViewer DX (cleared under K232202)	Dell U3223QE	Chrome	2.72, 1.31, 2.02
					Edge	2.72, 1.31, 2.02
Hamamatsu NanoZoomer S360MD	NDPI	Concentriq AP-Dx	Concentriq DX (cleared under K230839)	JVC-C240BN01A	Chrome	1.66, 0.71, 0.31
					Edge	1.66, 0.71, 0.31

2. Measurement – Distance and Area

Measurement accuracy testing was conducted to demonstrate that spatial measurements made using the Concentriq-AP-Dx annotation tools accurately measure distance and area 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. Distance measurements included horizontal, vertical, and orthogonal lengths. Areas included rectangular annotations spanning clearly defined marks on the horizontal and vertical axes of the reticle slide. Screenshots of the distance and area measurements at two magnifications (10x and 40x or 20x and 40x, respectively) were captured. The test data showed that the difference between distance and area measurements made in the Concentriq AP-Dx and the ground truth was less than the acceptance criteria (1%). These results, summarized in Table 5 below, demonstrated acceptable measurement accuracy with respect to its intended use.

Table 5: Concentriq AP-Dx Measurement Test 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%

3. Turnaround Time Testing

Turnaround time testing was conducted to measure the time needed by Concentriq AP-Dx to conduct the load, panning, and zooming operations. A total of 9 test SVS images of 3 different sizes, derived from H&E-stained FFPE tissue were used for testing. The testing was performed across both Chrome and Edge browsers. The objective level for all test images was 40x for the zooming feature to operate between 20x and 40x. The Hamamatsu

NanoZoomer S360MD was not included in the testing because individual tiles generated by Concentriq AP-Dx's Image Ingestion Service are in the same file format, regardless of the original image format from the scanner. The test execution demonstrated maximum turnaround times of less than 2 seconds across all scenarios. These results are summarized in Table 6 below.

Table 6: Concentriq AP-Dx Turnaround Time Testing Results

Scanner	Image File Format	Subject Device/Browser	Results (Seconds)		
			Loading (sec) Max, Min, Mean	Panning (sec) Max, Min, Mean	Zooming (sec) Max, Min, Mean
Leica Aperio GT 450 DX scanner	SVS	Concentriq AP-Dx / Chrome	0.389 0.242 0.319	1.430 1.181 1.208	1.218 1.181 1.196
		Concentriq AP-Dx / Edge	0.617 0.248 0.339	1.437 1.181 1.208	1.217 1.181 1.197

4. Human Factors Study

No new human factors study was performed for Concentriq AP-Dx since it was previously conducted in K230839.

5. Software and cybersecurity

Software and cybersecurity documentation was reviewed and found to be acceptable.

VIII Pre-determined Change Control Plan (PCCP)

Proscia Inc. provided a PCCP (version 01) which will be followed to validate interoperability of additional FDA-cleared scanners and displays with the Concentriq AP-Dx, including specific performance requirements that must be met prior to updating the device labeling to reference the newly added scanners or displays. The PCCP also includes verification that any display-specific software will not impact performance of the Concentriq AP-Dx. 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 scanners and displays that are interoperable with Concentriq AP-Dx and allow users to request updated versions of the system labeling.

IX Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

X Conclusion:

The submitted information in this premarket notification supports a substantial equivalence decision.