February 8, 2024

Proscia, Inc.
Kim Rendon
Director of Regulatory Affairs
1700 Market St.
23rd Floor
Philadelphia, Pennsylvania 19103

Re: K230839
Trade/Device Name: Concentriq Dx
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: QKQ
Dated: March 27, 2023
Received: March 27, 2023

Dear Kim Rendon:

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.

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)*
K230839

Device Name

Concentriq Dx

Indications for Use *(Describe)*

For In Vitro Diagnostic Use

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.

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® Dx

DATE PREPARED: February 7, 2024

SUBMITTER

Proscia, Inc.
1700 Market Street 23rd Floor
Philadelphia, PA 19103
(215) 608-5411

PRIMARY CONTACT PERSON

Kim Rendon
Director of Regulatory Affairs

DEVICE

Proprietary Name/Trade Name:	Concentriq® Dx
Classification Name:	Whole Slide Imaging System
Regulation Number:	21 CFR 864.3700
Product Code:	QKQ
Device Classification:	Class II
Review Panel:	88 - Pathology
Common Name:	Digital Pathology Image Viewing and Management Software

PREDICATE DEVICE

Proprietary Name:	NanoZoomer S360MD Slide scanner system
Submission Number:	K213883

INDICATIONS FOR USE

For In Vitro Diagnostic Use

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.

DEVICE DESCRIPTION

CONCENTRIQ 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 Instructional Manual and standard lab procedures. The Concentriq Dx workflow is initiated when the WSI from the local file system is ingested into Concentriq 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., a Laboratory Information System (LIS).

7. When finished using the system, the pathologist clicks "Sign Out" in the user menu.

Quality Control:

Prior to using a whole slide image for diagnosis, the pathologist should ensure that all scanned slide images have been imported for every case and the images are of acceptable quality for diagnostic purposes. The pathologist reviews scanned images from all the slides associated with a case before rendering a diagnosis.

Table 1: WSI scanner

Manufacturer	**Model**
Hamamatsu	NanoZoomer S360MD Slide scanner

Table 2: WSI display

Manufacturer	Model
JVC	JD-C240BN01A

Table 3: Computer environment/System Requirements:

Workstation Component	Specifications
Processor	2 GHz processor or higher with at least 4 cores
Memory	8 GB or higher
Monitor	JVC JD-C240BN01A for use with Hamamatsu NanoZoomer S360MD Slide scanner
Network connectivity	100 Mbps (1 Gbps LAN recommended) connection
Keyboard / Mouse / Trackpad	Windows 10 compatible Optional: 3Dconnexion SpaceMouse Pro, 3Dconnexion SpaceMouse Compact
Operating system	Windows 10
Supported browsers	Google Chrome 119.0.6045.105, Microsoft Edge 118
Antivirus software	Norton Antivirus V22.22.6.10 and McAfee Antivirus 16.0

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The following table summarizes the similarities and differences between the Concentriq Dx and the predicate device, NanoZoomer System.

Specification	Predicate Device	Proposed Subject Device
Device Trade Name	NanoZoomer System (NZViewMD)	Concentriq Dx
Product Code	PSY	QKQ
Regulation	21 C.F.R. § 864.3700	21 C.F.R. § 864.3700
Regulation Name	Whole Slide Imaging System	Whole Slide Imaging System

Specification	Predicate Device	Proposed Subject Device
Classification	II	II
Indications for Use	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. The NanoZoomer System comprises the NanoZoomer S360MD Slide scanner, the NZViewMD Software and the JVC Kenwood JD-C240BN01A display. 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.	For In Vitro Diagnostic Use 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 Hamamatsu NanoZoomer S360MD Slide scanner and JVC JD-C240BN01A monitor.
Scanner	NanoZoomer S360MD Slide scanner	NanoZoomer S360MD Slide scanner
Compatible Display	JVC Kenwood JD-C24BN01A	JVC Kenwood JD-C24BN01A
Specimen Type	Same	Surgical pathology slides prepared from FFPE tissue

Specification	Predicate Device	Proposed Subject Device
Image File Formats	Same	Hamamatsu's NZAcquireMD .ndpi file format
Image Manipulation Functions	Same	Panning, zooming, image adjustments, annotations, and distance/area measurements
Type of Software Application	Windows based	Internet browser based
Device Components	Scanner, Image Management Software and Display	Image Management Software
Principle of Operation	After WSI are acquired by using NanoZoomer S360MD Slide scanner, the WSI are automatically saved to the hard disk during scanning and may be viewed later by using the included viewing software. During review, the pathologist opens WSI from the image storage attached to local network, performs further QC and reads WSI 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.
User Interface	NZViewMD	Concentriq Dx

SUBSTANTIAL EQUIVALENCE COMPARISON

The proposed subject device has the same Indications for Use and similar Functional and Technological Characteristics to the predicate device's Image Management System (IMS) application software and is therefore substantially equivalent to the predicate device.

PERFORMANCE DATA

Performance data	Description
Pixel-wise comparison	A pixel-wise comparison test was performed to compare images which were reproduced by Concentriq Dx and NZViewMD for the same NDPI file to validate identical image reproduction. Test results showed that the 95th percentile of pixelwise differences between Concentriq Dx and NanoZoomer S360MD Slide scanner system was greater than 3 CIEDE2000, indicating that their output images are not pixel-wise identical as Concentriq Dx applies image compression to its output. Based on the findings from bench testing, a clinical study was performed to establish the safety and effectiveness of the device.
Clinical Study	A clinical study was conducted to demonstrate that viewing, reviewing, and diagnosing WSIs of H&E stained FFPE tissue slides using Concentriq Dx [manual digital read (MD)] is non-inferior to glass slide reads using optical (light) microscopy [manual optical (MO)]. The primary endpoint of the study was the difference in major discordance rates between MD and MO when compared to the reference (main) diagnosis, which was the original sign-out pathologic diagnosis using MO [ground truth, (GT)] rendered at the institution. The differences in major discordance rates between MD and GT compared to MO and GT were -0.1% (95% CI, -1.0, 0.4) for all cases across the 3 reading pathologists. The upper limit of the CI for the difference in the major discordance rate was 0.4%, which is less than the prespecified noninferiority threshold of 4%, therefore meeting the primary objective of the study.
Turnaround	The system requirements have been fulfilled: • Images load in less than 5 seconds when selected for viewing • Images load in less than 2 seconds when spanning and zooming
Measurements of Area and Distance	Measurement accuracy has been verified by comparing the measurements of markings made in the Concentriq viewer to the measurements of markings on a calibrated cross scale slide with known sizes. The tests were used to validate the measurement accuracy of the subject device. Tests verified that the distance and area measurements made in the Concentriq Dx viewer accurately reflected the distance and area of the markings on an image of the calibrated slide. These results show that Concentriq performed accurate measurements with respect to its intended use.

Performance data	Description
Human Factors Validation Study	Concentriq Dx has been found to be safe and effective for the intended users, uses and use environments.

CONCLUSION

Based on the information provided in the 510(k), the subject device Concentriq Dx is substantially equivalent to the previously cleared predicate device, when used Hamamatsu NanoZoomer S360MD Slide scanner and JVC JD-C240BN01A monitor. A clinical study was conducted to establish the Substantial Equivalence of the device.