Ventana Medical Systems, Inc.
Cameron Smith
Regulatory Affairs Manager
(Ventana, VMSI; Roche Tissue Diagnostics, RTD)
1910 E. Innovation Park Drive
Tucson, Arizona 85755

December 17, 2024

Re: K242783
Trade/Device Name: Roche Digital Pathology Dx
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: PSY
Dated: September 13, 2024
Received: September 16, 2024

Dear Cameron Smith:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242783

Device Name
Roche Digital Pathology Dx

Indications for Use *(Describe)*
Roche Digital Pathology Dx is an automated digital slide creation, viewing and management system. Roche Digital Pathology Dx is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of scanned pathology slides prepared from formalin-fixed paraffin-embedded (FFPE) tissue. Roche Digital Pathology Dx is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. Roche Digital Pathology 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.

Roche Digital Pathology Dx is composed of VENTANA DP 200 slide scanner, VENTANA DP 600 slide scanner, Roche uPath enterprise software, and ASUS PA248QV display. 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 Roche Digital Pathology 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.

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510(k) Summary
Roche Digital Pathology Dx

Date Prepared: December 12, 2024

SUBMITTER

Ventana Medical Systems, Inc.

CONTACT PERSON

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Cameron Smith
Regulatory Affairs Manager
(Ventana, VMSI; Roche Tissue Diagnostics, RTD)
1910 E. Innovation Park Drive
Tucson, Arizona 85755

DEVICE INFORMATION

Subject Device

Proprietary Name:	Roche Digital Pathology Dx
Common Name:	Roche Digital Pathology Dx
Classification Name:	Whole Slide Imaging System
Regulation Section:	21 CFR 864.3700
Classification:	Class II
Product Code:	PSY
Review Panel:	88 – Pathology
510(k) Number:	K242783

Predicate Device

Proprietary Name:	Roche Digital Pathology Dx (VENTANA DP 200)
Submission Number:	K232879

A new model of the slide scanner component, VENTANA DP 600 slide scanner, is being added to the Roche Digital Pathology Dx [previously known as Roche Digital Pathology Dx (VENTANA DP 200)] system. As a part of the system modification, the system name is being changed to "Roche Digital Pathology Dx".

I. INTENDED USE

Roche Digital Pathology Dx is an automated digital slide creation, viewing and management system. Roche Digital Pathology Dx is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of scanned pathology slides prepared from formalin-fixed paraffin-embedded (FFPE) tissue. Roche Digital Pathology Dx is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. Roche Digital Pathology 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.

Roche Digital Pathology Dx is composed of VENTANA DP 200 slide scanner, VENTANA DP 600 slide scanner, Roche uPath enterprise software, and ASUS PA248QV display. 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 Roche Digital Pathology Dx.

II. DEVICE DESCRIPTION

Roche Digital Pathology Dx (hereinafter referred to as RDPD), is a whole slide imaging (WSI) system. It is an automated digital slide creation, viewing, and management system intended to aid pathologists in generating, reviewing, and interpreting digital images of surgical pathology slides that would otherwise be appropriate for manual visualization by conventional light microscopy. RDPD system is composed of the following components:

- VENTANA DP 200 slide scanner,
- VENTANA DP 600 slide scanner,
- Roche uPath enterprise software, and

- ASUS PA248QV display.

VENTANA DP 600 slide scanner has a total capacity of 240 slides through 40 trays with 6 slides each. The VENTANA DP 600 slide scanner and VENTANA DP 200 slide scanner use the same Image Acquisition Unit.

Both VENTANA DP 200 and DP 600 slide scanners are bright-field digital pathology scanners that accommodate loading and scanning of 6 and 240 standard glass microscope slides, respectively. The scanners each have a high-numerical aperture Plan Apochromat 20x objective and are capable of scanning at both 20x and 40x magnifications. The scanners feature automatic detection of the tissue specimen on the glass slide, automated 1D and 2D barcode reading, and selectable volume scanning (3 to 15 focus layers). The International Color Consortium (ICC) color profile is embedded in each scanned slide image for color management. The scanned slide images are generated in a proprietary file format, BioImagene Image File (BIF), that can be uploaded to the uPath Image Management System (IMS), provided with the Roche uPath enterprise software.

Roche uPath enterprise software (uPath), a component of Roche Digital Pathology Dx system, is a web-based image management and workflow software application. uPath enterprise software can be accessed on a Windows workstation using the Google Chrome or Microsoft Edge web browser. The user interface of uPath software enables laboratories to manage their workflow from the time the whole slide image is produced and acquired by VENTANA DP 200 and/or DP 600 slide scanners through the subsequent processes, such as review of the digital image on the monitor screen and reporting of results. The uPath software incorporates specific functions for pathologists, laboratory histology staff, workflow coordinators, and laboratory administrators.

III. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The candidate device, Roche Digital Pathology Dx, is substantially equivalent to the predicate device, Roche Digital Pathology Dx (VENTANA DP 200), which was cleared on June 14, 2024 through K232879. Below is a table that provides a comparison between the two devices:

Table 1: Comparison of Predicate Device and Candidate Device
(differences underlined)

Aspect	**Predicate Device:** **Roche Digital Pathology Dx (VENTANA DP 200)**	**Candidate Device:** **Roche Digital Pathology Dx (RDPD)**
510(k) Number	K232879	K242783
Manufacturer	Ventana Medical Systems, Inc.	same
Product Code	PSY - Whole Slide Imaging System	same
Regulation Section	21 CFR 864.3700	same
Panel	(88) Pathology	same
Intended Use	Roche Digital Pathology Dx (VENTANA DP 200) is an automated digital slide creation, viewing and management system. Roche Digital Pathology Dx (VENTANA DP 200) is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of scanned pathology slides prepared from formalin-fixed paraffin-embedded (FFPE) tissue. Roche Digital Pathology Dx (VENTANA DP 200) is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. Roche Digital Pathology Dx (VENTANA DP 200) is for creation and viewing of digital images of scanned glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy. Roche Digital Pathology Dx (VENTANA DP 200) is composed of VENTANA DP	Roche Digital Pathology Dx is an automated digital slide creation, viewing and management system. Roche Digital Pathology Dx is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of scanned pathology slides prepared from formalin-fixed paraffin-embedded (FFPE) tissue. Roche Digital Pathology Dx is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. Roche Digital Pathology 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. Roche Digital Pathology Dx is composed of VENTANA DP 200 slide scanner,

Aspect	**Predicate Device:** **Roche Digital Pathology Dx (VENTANA DP 200)**	**Candidate Device:** **Roche Digital Pathology Dx (RDPD)**
	200 slide scanner, Roche uPath enterprise software, and ASUS PA248QV display. 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 Roche Digital Pathology Dx (VENTANA DP 200).	VENTANA DP 600 slide scanner, Roche uPath enterprise software, and ASUS PA248QV display. 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 Roche Digital Pathology Dx.
Principle of Operation	After conducting Quality Control (QC) on the glass slides per laboratory standards (e.g., staining, coverslipping, barcode placement, etc.), the technician loads the slides into the VENTANA DP 200 slide scanner. The scanner scans the slides and generates a whole slide image for each slide. The technician performs QC on scanned WSI images by checking image data and image quality. The operator has the option to reject slide scans and initiate a re-scan. The acquired WSI images are stored in an end user provided image storage attached to the local network. During review, the pathologist opens WSI images from the image storage in Roche uPath enterprise software, performs further QC to ensure image quality, and reads the WSI images of the slides to make a diagnosis.	After conducting Quality Control (QC) on the glass slides per laboratory standards (e.g., staining, coverslipping, barcode placement, etc.), the technician loads the slides into the VENTANA DP 200 or DP 600 slide scanner. The scanner scans the slides and generates a whole slide image for each slide. The technician performs QC on scanned WSI images by checking image data and image quality. The operator has the option to reject slide scans and initiate a re-scan. The acquired WSI images are stored in an end user provided image storage attached to the local network. During review, the pathologist opens WSI images from the image storage in Roche uPath enterprise software, performs further QC to ensure image quality, and reads the WSI images of the slides to make a diagnosis.
Device Components	WSI scanner (VENTANA DP 200 slide scanner), Image Management System (Roche uPath enterprise software), and color monitor display (ASUS PA248QV)	WSI scanners (VENTANA DP 200 slide scanner and VENTANA DP 600 slide scanner), Image Management System (Roche uPath enterprise software), and color monitor display (ASUS PA248QV)
Slide Scanner Capacity	VENTANA DP 200 slide scanner: 1 tray with 6 slides or 1 tray with 3 double-wide slides	VENTANA DP 200: 1 tray with 6 slides or 1 tray with 3 double-wide slides VENTANA DP 600 slide scanner: 40 trays with 6 slides each; 240 slides total
Specimen Type	Surgical pathology slides prepared from FFPE tissue	same
Scanning Magnification	20x and 40x	same
Scan Output Image Format	BIF	same

IV. PERFORMANCE DATA

1. Design Changes

A new model of the slide scanner component, VENTANA DP 600 slide scanner, is being added, while the image management software and display monitor have not changed. The VENTANA DP 200 slide scanner and VENTANA DP 600 slide scanner differ mainly in slide capacity. They share the same Image Acquisition Unit (IAU) for creating the scanned slide image. The IAU includes all hardware components, subassemblies and software modules whose form, fit and function have a direct effect on the pixel values of the digital image of the scanned slide. The hardware and software components comprising the Image Acquisition Unit implement the pixel pipeline, that is, the process of imaging the tissue specimen and creating the digital image. The IAU matches the 'Image Acquisition' subsystem defined in the FDA's device-specific guidance "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices (April 20, 2016)" (FDA TPA guidance).

All hardware and software components not part of the IAU implement Workflow and User Support Functions (WUSF). These components and software modules do not have a direct effect on the pixel values of the digital tissue image. See below Table 2 which breaks the main scanner components into either IAU or WUSF. Hardware components and software modules comprising the WUSF may or may not be equivalent.

Similarities between the predicate and subject devices were analyzed by comparing their IAU hardware and software components. The IAU hardware components, including the superstructure, illuminator, imaging optics (objective, tube lens, and imaging sensor), focus assembly, focus imaging system, and focusing subsystem, and stage assembly are identical. The IAU software components, including the pixel shaping and image composition modules, are functionally identical. The IAU support software components, including the Focus Tracking Algorithm, Service Tool, and Calibration and Diagnostic Utility, are functionally identical.

Differences between the predicate and subject devices were analyzed by comparing their WUSF components, including slide loading mechanism, tray storage rack, frame and cover.

Table 2: Assemblies by their Function of Image Acquisition Unit (IAU) or Workflow and User Support Functions (WUSF)

Function	Assembly
IAU	Superstructure
	Optical Path
	Illuminator Assembly
	Focus Assembly
	Focusing Imaging Subsystem
	Stage Assembly
WUSF	Frames and Covers
	Slide Loading Mechanism
	Tray Storage Rack
	Workflow Management Software

Design controls were implemented throughout the design process of the VENTANA DP 600 slide scanner to maintain the entire IAU of the predicate device scanner (VENTANA DP 200 slide scanner) to be unaltered in form, fit and function. The design controls and design changes are documented in the Quality Management System (QMS) of the Predicate Device scanner (VENTANA DP 200 slide scanner) and the VENTANA DP 600 slide scanner, specifically the Customer Requirement and Product Requirement documents, which are part of the Design History File. As part of the design controls, all requirements passed the required verification and validation process.

Since the VENTANA DP 600 slide scanner IAU is identical to that of the Predicate Device scanner by design, the Technical Performance Assessment provided in conjunction with the Predicate Device is fully applicable to the VENTANA DP 600 slide scanner as shown in Table 3.

2. Technical Studies

Multiple studies were conducted on the VENTANA DP 200 slide scanner to evaluate the performance assessment data associated with the technical evaluation of Roche Digital Pathology Dx per the aforementioned FDA TPA guidance. All performance characteristics data were collected on the VENTANA DP 200 slide scanner but by virtue of identical imaging acquisition units by design, its results are also representative of the VENTANA DP 600 slide scanner performance. See below Table 3 which compares the predicate device to the subject device for these aspects.

Table 3: Comparison of technical characteristics

TPA Section	DP 200 slide scanner (K232879)	DP 600 slide scanner (K242783)
Components		
Slide Feeder	Information was provided on the configuration of the slide feed mechanism, including a physical description of the slide, the number of slides in queue (carrier), and the class of automation. Information was provided on the user interaction with the slide feeder, including hardware, software, feedback mechanisms, and Failure Mode and Effects Analysis (FMEA).	no double wide slide tray compatibility, new FMEA provided in K242783
Light Source	Descriptive information associated with the lamp and the condenser was provided. Testing information was provided to verify the spectral distribution of the light source as part of the color reproduction capability of VENTANA DP 200 scanner.	Information was provided in K232879
Imaging Optics	Information including an optical schematic with all optical elements identified from slide (object plane) to digital image sensor (image plane) was provided. Descriptive information regarding the microscope objective, the auxiliary lenses, and the magnification of imaging optics was provided. Testing information regarding the relative irradiance, optical distortions, and lateral chromatic aberrations was provided.	Information was provided in K232879
Focusing System	Schematic diagrams and a description of operation of the focus system, which includes the optical system, 2 imaging cameras, and a focus tracking algorithm, was provided.	Information was provided in K232879
Mechanical Scanner Movement	Information and specifications on the configuration of the stage, method of movement, control of movement of the stage, and FMEA was provided. Test data to verify the repeatability of the stage movement mechanism staying within limit during operation was provided.	same except no double wide slide tray compatibility, replaced references & new FMEA items provided in K242783
Digital Imaging Sensor	Information and specifications on the sensor type, pixel information, responsivity specifications, noise specifications, readout rate, and digital output format was provided. Test data to determine the correct functioning of the digital image sensor that converts optical signals of the slide to digital signals which consist of a set of numerical values corresponding to the brightness and color at each point in the optical image was provided.	Information was provided in K232879

TPA Section	DP 200 slide scanner (K232879)	DP 600 slide scanner (K242783)
Image Processing Software	Information and specifications on exposure control, white balance, color correction, subsampling, pixel-offset correction, pixel-gain or flat-field correction, and pixel-defect correction were provided.	Information was provided in K232879
Image Composition	Information and specifications on the scanning method, the scanning speed, and the number of planes at the Z-axis to be digitized were provided. Test data to analyze the image composition performance was provided.	Information was provided in K232879
Image File Formats	Information and specifications on the compression method, compression ratio, file format, and file organization were provided.	Information was provided in K232879
Image Review Manipulation Software	Information and specifications on continuous panning and pre-fetching, continuous zooming, discrete Z-axis displacement, the ability to compare multiple slides simultaneously on multiple windows, image enhancement and sharpening functions, color manipulation, annotation tools, and digital bookmarks were provided.	Information was provided in K232879
Computer Environment	Information and specifications on the computer hardware, operating system, graphics card, graphics card driver, color management settings, color profile, and display interface were provided.	select upgrades of sub-components & specifications
Display	Information and specifications on the technological characteristics of the display such as pixel density, aspect ratio, display viewing area, display surface, backlight type, panel type, viewing angle, pixel pitch, resolution, color space, max brightness, contrast ratio, response time, refresh rate (max), color accuracy, color adjustment, gamma adjustment, adjustments, display interface, and certificate were provided. Test data to verify the performance of the display for user controls, spatial resolution, pixel defects (count and map), artifacts, temporal response, maximum and minimum luminance (achievable and recommended), grayscale, luminance uniformity, bidirectional reflection distribution function, gray tracking, color scale, and color gamut volume was provided.	Information was provided in K232879
System-level Assessments		
Color Reproducibility	Test data to evaluate the color reproducibility of the system was provided.	Information was provided in K232879
Spatial Resolution	Test data to evaluate the composite optical performance of all components in the image acquisition phase was provided.	Information was provided in K232879
Focusing Test	Test data to evaluate the technical focus quality of the system was provided.	Information was provided in K232879
Whole Slide Tissue Coverage	Test data to demonstrate that the entire tissue specimen on the glass slide is detected by the tissue detection algorithms and that all the tissue specimens are included in the digital image file was provided.	Information was provided in K232879
Stitching Error	Test data to evaluate the stitching errors and artifacts in the reconstructed image was provided.	Information was provided in K232879
Turnaround Time	Test data to evaluate the turnaround time of the system was provided.	Information was provided in K232879
User Interface	Information on the parts of the system that users interact with, along with human factors/usability validation testing performed to demonstrate that representative users of the WSI system can perform essential tasks and those critical to safety under simulated use conditions was provided.	identical workflow, replacement of new scanner component depiction
Labeling	The labeling is sufficient, and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable, and the special controls for this device type under 21 CFR 864.3700.	same content, replaced references

TPA Section	DP 200 slide scanner (K232879)	DP 600 slide scanner (K242783)
Quality Control	Quality control (QC) activities are performed by the user per the laboratory standards and professional guidelines (e.g., staining, cover-slipping, barcode placement) prior to loading the slides into the VENTANA DP 200. After completing a scan, the lab technician checks image data and image quality as per the instructions for use. Before review, the pathologist ensures the quality of the WSI images before reviewing the image for diagnostic purposes.	same content, replaced references

3. User Interface/Human Factors Validation

An analysis was performed to determine if additional human factors / usability evaluations were necessary to supplement the study done for the predicate device for this modification. The analysis spanned usability heuristics, comparative analysis of the workflows, risks, and related tasks for whole slide imaging. While minor differences in the User Interface (UI) exist and are notable (such as differences in some terminology, the appearance of the UI, the difference in slide capacity, and the consolidation of certain UI elements), it was determined that there are no high-level workflow differences in user input or scanner output and the identified differences in the UI have no impact on users' ability to safely complete the whole slide imaging workflow. Importantly, the users' mental model of successfully completing a scan workflow does not change, regardless of the volume of trays / slides being loaded. In fact, the updated UI improved the information architecture structure, encouraging users to be more intentional about the tasks they perform during the scan workflow by explicitly confirming through the UI which tasks they are trying to accomplish. Additionally, a review and analysis of the critical tasks from the predicate device's usability evaluation & risk analysis revealed no new risks as they are virtually identical, and, upon review of DP 600 slide scanner's risk documentation and summative usability results, no significant risks related to the safe completion of the workflow were found. In summary, no additional usability study is required for this modification and the usability validation efforts completed for the predicate device are applicable to the modified device.

4. Electromagnetic Compatibility (EMC) Testing

VENTANA DP 600 slider scanner EMC testing was performed by external vendor testing services using the following test standards: EN 61326-1:2013, IEC 61010-1, IEC 62368-1, and EN 61000-4. According to the test report, the emission testing was performed in accordance with EN 55011:2016 and VENTANA DP 600 slide scanner met the testing requirements classified for Group 1, Class A equipment. VENTANA DP 600 slide scanner also passed the various testing categories based on the corresponding test standards.

5. Clinical Testing

The modification to the system of increased slide scanner capacity does not require additional clinical performance data, so the clinical performance of the modified device is substantially equivalent to the original, predicate device cleared in K232879. As displayed above, the design, components, and relevant performance data of the scanners are identical with a few exceptions that do not impact the Image Acquisition Unit's produced image quality, the final output of the device, or its ability to fulfill its intended use as a whole slide imaging system. Therefore it is concluded that the scanners are equivalent in these aspects.

V. CONCLUSION

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