April 16, 2024

Sectra AB
℅ Peter Altman
Consultant
Medical Device Regulatory Services
14 Mercer Road
Savannah, Georgia 31411

Re: K232208
Trade/Device Name: Sectra Digital Pathology Module (3.3)
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: QKQ
Dated: July 26, 2023
Received: July 26, 2023

Dear Peter Altman:

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 2
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
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)*
K232208

Device Name
Sectra Digital Pathology Module (3.3)

Indications for Use *(Describe)*
For In Vitro Diagnostic Use

Sectra Digital Pathology Module (3.3) is a software 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 and interpret these digital images for the purposes of primary diagnosis.

Sectra Digital Pathology Module (3.3) is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using Sectra Digital Pathology Module (3.3).

Sectra Digital Pathology Module (3.3) is intended for use with Leica's Aperio GT 450 DX scanner and Dell U3223QE display, for viewing and management of the ScanScope Virtual Slide (SVS) and Digital Imaging and Communications in Medicine (DICOM) image formats.

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

Sectra Digital Pathology Module (3.3), Sectra AB

Date Prepared: April 15, 2024

Submitter:

Sectra AB
Teknikringen 20
SE-583 30 Linköping
Sweden
Establishment Registration Number: 9615992

Contact Person:

Name: Edoardo Mastrovito
Title: Quality and Regulatory Affairs Mgr.
Telephone: +46 13 235206
Facsimile: n/a

Device Identification:

Proprietary/Trade Name:	Sectra Digital Pathology Module
Version Number	3.3
510(k) Number:	K232208
Classification Name:	Whole Slide Imaging System
Regulation Number:	21 CFR 864.3700
Product Codes:	QKQ
Device Class:	Class II
Review Panel:	88 – Pathology
Common Name:	Digital Pathology Image Viewing and Management Software

Predicate Device Identification:

Proprietary/Trade Name:	The Aperio WebViewer DX component of the Aperio GT 450 DX System
510(k) Number:	K232202
Classification Name:	Whole Slide Imaging System
Regulation Number:	21 CFR 864.3700
Product Codes:	PSY
Device Class:	Class II
Review Panel:	88 – Pathology
Common Name:	Digital Pathology Image Management System

Device Description:

The Sectra Digital Pathology Module (3.3) [henceforth referred to DPAT (3.3)] is a digital slide viewing system. The DPAT (3.3) is intended for use together with FDA-cleared whole-slide image scanner GT 450 DX and Dell U3223QE display.

The DPAT (3.3) can only be used as an add-on module to Sectra PACS. Sectra PACS consists of Sectra Workstation IDS7 (K081469) and Sectra Core (identified as a Class I exempt by the FDA in 2000). Sectra PACS is not part of the subject device. Sectra Workstation is the viewing workstation in which the Pathology Image Window is run. Pathology Image Window is the client component of the subject device.

The system capabilities include:

• retrieving and displaying digital slides,

• support for remote intranet access over computer networks,

• tools for annotating digital slides and entering and editing metadata associated with digital slides, and

• displaying the scanned slide images for primary diagnosis by pathologists.

The subject device is designed to accurately display colors. The monitor is not part of the subject device.

Digital pathology images originating from WSI scanners other than those listed in the Indications for Use will be marked with the disclaimer "For Non-clinical Use Only" in the Pathology Image Window.

Image acquisition will be managed by the scanner which is not part of the subject device:

• The scanner delivers images with a tag in the file header that identifies the originating scanner.

• The scanner includes applications for controlling the scanning process and performing related quality control (e.g., ensuring that images are sharp and cover all tissue on the slide).

The DPAT (3.3) supports reading digital slides on a Dell U3223QE display monitor, enabling pathologists to make clinically relevant decisions analogous to those they make using a conventional microscope. Specifically, the system supports the pathologist in performing a primary diagnosis based on viewing the digital slide on a computer monitor. These capabilities are provided by the Pathology Image Window.

Indications for Use/Intended Use:

For In Vitro Diagnostic Use

Sectra Digital Pathology Module (3.3) is a software 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 and interpret these digital images for the purposes of primary diagnosis.

Sectra Digital Pathology Module (3.3) is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens.

It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using Sectra Digital Pathology Module (3.3).

Sectra Digital Pathology Module (3.3) is intended for use with Leica's Aperio GT 450 DX scanner and Dell U3223QE display, for viewing and management of the ScanScope Virtual Slide (SVS) and Digital Imaging and Communications in Medicine (DICOM) image formats.

Table 1: Summary of Technological Characteristics

<table>
<tr><th>Item</th><th>Subject Device</th><th>Predicate</th></tr>
<tr><td>Indications for Use</td><td>For In Vitro Diagnostic Use
Sectra Digital Pathology Module (3.3) is a software 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 and interpret these digital images for the purposes of primary diagnosis.

Sectra Digital Pathology Module (3.3) is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using Sectra Digital Pathology Module (3.3).

Sectra Digital Pathology Module (3.3) is intended</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 interoperable components specified in Table 1.

Table 1: Interoperable components of Aperio GT 450 DX
<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 MDPC-8127
Dell UP3017
Dell U3023E
Dell U3223QE</td></tr>
<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</td></tr>
</table>

Item	Subject Device	Predicate
	for use with Leica's Aperio GT 450 DX scanner and Dell U3223QE display, for viewing and management of the ScanScope Virtual Slide (SVS) and Digital Imaging and Communications in Medicine (DICOM) image formats.	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.
Specimen type	Surgical pathology slides prepared from FFPE tissue	Surgical pathology slides prepared from FFPE tissue
Image Storage	Images are stored in an end user provided image storage attached to the local network.	Images are stored in an end user provided image storage attached to the local network.
Image manipulation functions	Panning, zooming, gamma function, annotations, and measurements (distance & area)	Panning, zooming, gamma function, annotations, and measurements (distance & area)
Image review and diagnosis	During 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.	During 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.
End User's Interface	Pathology Image Window (the client component of Sectra Digital Pathology Module 3.3)	Aperio WebViewer DX
Scanner	Sectra Digital Pathology Module does not include a scanner; however, it is indicated for use with Aperio GT 450 DX	Aperio GT 450 DX

Table 2: Performance data

<table>
<tr><th>Performance data</th><th>Description</th></tr>
<tr><td>Clinical Study</td><td>A clinical study was conducted to demonstrate that viewing, reviewing, and diagnosing whole slide images (WSIs) of FFPE tissue slides with DPAT (3.3) on Sectra Workstation UniView (referred to as DPAT (3.3)-UniView) is noninferior to diagnoses made using light microscopy.</td></tr>
<tr><td>Pixel-Wise Comparison</td><td>Pixel-wise comparison study was performed to demonstrate that DPAT (3.3) generates identical images in the configurations that were not validated in the clinical study. The imaging pipeline Aperio GT 450 DX/SVS/DPAT (3.3)-UniView/Chrome configuration was validated in the clinical study and was used as the reference configuration in the pixelwise comparison study to validate the other 4 configurations as described below.
<table>
<tr><th>Configuration</th><th>Image File format</th><th>Viewer/Browser</th></tr>
<tr><td>DICOM/IDS7</td><td>DICOM</td><td>IDS7</td></tr>
<tr><td>DICOM/UniView/Chrome</td><td>DICOM</td><td>UniView/Chrome</td></tr>
<tr><td>SVS/IDS7</td><td>SVS</td><td>IDS7</td></tr>
<tr><td>SVS/UniView/Edge</td><td>SVS</td><td>UniView/Edge</td></tr>
</table>
Based on analysis of the testing data, the 4 configurations specified in table above were identical, i.e., $<3\Delta E_{00}$ to reference configuration SVS/UniView/Chrome.</td></tr>
<tr><td>Turnaround time</td><td>Provided that the system requirements are fulfilled:
- When selecting a slide image, it should not take longer than 3 seconds until the image is fully loaded.
- When panning the image (one quarter of the monitor) it should not take longer than 0.5 seconds until the image is fully loaded.</td></tr>
<tr><td>Measurements</td><td>Measurement accuracy has been verified using a test image containing objects with known sizes.</td></tr>
<tr><td>Human factors testing</td><td>Human factors study designed around critical user tasks and use scenarios performed by representative users were conducted for previously cleared DPAT 2.2 in K193054. No new human factor study was performed for DPAT (3.3).</td></tr>
</table>

Substantial Equivalence Comparison:

Similarities

Both the DPAT (3.3) and the WebViewer DX of the Aperio GT 450 DX System are software-only devices.

DPAT (3.3) is a web application just as the WebViewer. The color reproducibility performance of the DPAT (3.3) UniView rendering SVS images in Chrome has been shown in a clinical study to be adequate and equivalent to that of the WebViewer.

The clinical study was performed using SVS images displayed in the UniView Chrome, creating a reference pipeline that could then be used for technical testing with DICOM, IDS7, and Edge, to support the claims of the subject device. The subject device displayed the same scanned image in both DICOM and SVS formats, in IDS7, Edge or Chrome, with no difference ($\Delta E=0$).

Color reproducibility testing based on pixel-by-pixel comparisons using a set of images from the Aperio GT 450 DX demonstrates adequate performance of the DPAT (3.3) with both SVS and DICOM images.

The subject device includes the same image manipulation functions as the predicate device: panning, zooming, annotation, and measurements.

1) Turnaround times for zooming and panning were tested and found to be similar to or better than those of the predicate device.

2) Distance measurements show almost identical results when considering that some difference is to be expected due to the measurements not being created between the exact same points in the two viewers, as well as possible differences in numerical rounding.

Differences

The subject device supports both SVS and DICOM image formats (as provided by the Aperio GT 450 DX) whereas the WebViewer supports only the SVS format. The subject device performs equally well with both SVS and DICOM images.

A clinical study was needed as there is a difference in the pixel pipeline where the subject device avoids server-side transcoding, leading to dE>3 color difference compared to the predicate device. The clinical study was performed using SVS images displayed in UniView Chrome, creating a reference pipeline that could then be used for technical testing with DICOM, IDS7, and Edge, to support the claims of the subject device.

Summary of Studies:

Non-clinical test results:

Conducted per FDA's Guidance on Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices:

The clinical study was performed using SVS images displayed in UniView Chrome, creating a reference pipeline that could then be used for technical testing with DICOM, IDS7, and UniView in Edge, to support the claims of the subject device. The subject device displayed the same scanned image in both DICOM and SVS formats, in IDS7, Edge or Chrome, with no difference ($\Delta E=0$).

Turnaround times for panning and zooming have been determined and found to be adequate for the intended use of the subject device.

The subject device has been found to perform accurate measurements with respect to its intended use.

Clinical Study:

A clinical study was conducted to demonstrate that viewing, reviewing, and diagnosing whole slide images (WSIs) of FFPE tissue slides with DPAT (3.3) on Sectra Workstation UniView [referred to as DPAT (3.3)-UniView)] is noninferior to diagnoses made using light microscopy.

Clinical accuracy was evaluated by analyzing the concordance of the diagnoses made using DPAT (3.3)-UniView (referred to as WSI review [WSIR] diagnosis) with the original sign-out diagnoses (reference diagnoses), and the concordance of traditional light microscope slide review (MSR) diagnoses with the reference diagnoses. The primary endpoint of the study was the difference in overall major discrepancy rates between the 2 modalities when compared to the reference diagnosis. The secondary endpoint of the study was the major discrepancy rate of WSIR diagnosis relative to the reference diagnosis. The acceptance criteria associated with each study endpoint were as follows:

Primary Endpoint:

- The upper bound of the 2-sided 95% CI of the difference between the overall major discrepancy rates of WSIR diagnosis and MSR diagnosis when compared to the reference diagnosis shall be ≤4%.

Secondary Endpoints:

- The upper bound of the 2-sided 95% CI of the major discrepancy rate between WSIR diagnosis and the reference diagnosis shall be ≤7%.

The study included 258 cases that represented a diverse mixture of pathologic diagnoses and tissue/organ types. Case slides were scanned on the Aperio GT 450 DX scanner, producing WSIs. Three (3) reading pathologists (the same pathologists who determined MSR diagnosis) at a single site reviewed all study cases using DPAT (3.3)-UniView and a Dell U3223QE monitor, as specified by the Leica Biosystems (LBS) Aperio GT 450 DX and Sectra DPAT (3.3) IFU, to determine WSIR diagnosis. A minimum of two adjudicators independently assessed concordance (concordant, minor discrepancy, major discrepancy) of the WSIR diagnosis against the reference diagnosis using predefined rules. A major discrepancy was defined as a difference in diagnosis that resulted in a clinically important difference in patient management, whereas a minor discrepancy would not be associated with a clinically important difference in patient management. The adjudicators' concordance scores for the same case were compared to determine a consensus score for major discrepancy status (no major discrepancy [concordant or minor discrepancy] or major discrepancy). The diagnosis consensus scores were used to estimate WSIR diagnosis major discrepancy rate. Deferred diagnoses were treated as missing data and excluded from the statistical analysis.

Combining pathologists, it was planned to have 774 diagnoses (258 cases × 3 reading pathologists). Seven (7) WSIR and 10 MSR diagnoses were deferred and excluded from the statistical analysis. The estimated difference in major discrepancy rates between the 2 modalities when compared to the reference diagnosis was -0.01% (95% CI: -1.71% to 1.69%), as shown in Table 3. The upper bound of the 95% CI of the estimated difference in major discrepancy rates was 1.69% which met the predefined acceptance criteria of ≤4% for the primary endpoint. The secondary endpoint was to demonstrate that the overall major discrepancy rate between the WSIR diagnosis and the reference diagnosis did not exceed 7%; the upper bound of the 95% CI for the overall estimated major discrepancy rate for WSIR diagnosis was 5.25%, which met the predefined acceptance criteria of ≤7% as shown in Table 4.

Table 3. Overall Major Discrepancy Rates for WSIR Diagnoses and MSR Diagnoses and the Difference Between the Overall Major Discrepancy Rates

Modality	(n/N)	Discrepancy Rate	Model Estimated Discrepancy Rate	95% CI
WSIRD vs Reference	23/767	3.00%	2.95%	(1.64%, 5.25%)
MSRD vs Reference	23/764	3.01%	2.96%	(1.65%, 5.27%)
Difference			-0.01%	(-1.71%, 1.69%)

Note:
1. WSIRD: WSIR diagnosis; MSRD: MSR diagnosis
2. A generalized linear model was used to derive estimates of the major discrepancy rates and the difference along with their 95% CIs.

Table 4. Concordance Rate between WSIR Diagnoses and MSR Diagnoses

Number of Concordances	Number of Pairs	Concordance Rate (%)	95% Confidence Interval
729	762	95.7	[94.2%, 97.1%]

Note: 95% CI was produced using the percentile bootstrapping approach on 5000 bootstrap samples.

The acceptance criteria were met for all study endpoints. These study results support the conclusion that DPAT (3.3)-UniView is safe and effective when used by pathologists in rendering primary diagnoses of FFPE tissue sections as compared to using light microscopy when used according to the device intended use.

Conclusion:

The proposed Sectra Digital Pathology Module (3.3) when used with the Aperio GT 450 DX scanner has similar Indications for Use, Functional, and Technological Characteristics as the WebViewer DX viewer application software of the predicate device. The results of clinical and non-clinical testing demonstrate the device is safe and effective and substantially equivalent to the Aperio predicate device (K232202).