March 31, 2020

Sectra AB
℅ Peter Altman
Quality Officer
14 Mercer Road
Savannah, GA 31411-1433

Re: K193054/S001
Trade/Device Name: Sectra Digital Pathology Module
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Class: Class II
Product Code: QKQ
Dated: October 25, 2019
Received: November 1, 2019

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Soma Ghosh, Ph.D.
Chief
Molecular Pathology and Cytology Branch
Division of Molecular Genetics and Pathology
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193054

Device Name
Sectra Digital Pathology Module

Indications for Use *(Describe)*

For In Vitro Diagnostic Use
Sectra Digital Pathology Module device is a software 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 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.

Sectra Digital Pathology Module is intended for use with Leica's Aperio AT2 DX scanner and Dell MR2416 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.

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510(k) Summary

Date Prepared: 30 March 2020

Submitter's Information:

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Establishment Registration Number: 9615992

Contact Persons:

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Device Identification:

Proprietary/Trade Name:	Sectra Digital Pathology Module
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:	Aperio AT2 DX System
510(k) Number:	K190332
Clearance Date:	May 20, 2019
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:

Sectra Digital Pathology Module is a software-only device running under the Microsoft Windows operating system for displaying and manipulating digital pathology images (scanned slides) obtained from the Aperio AT2 DX scanner.

Sectra Digital Pathology Module may only be used in combination with Sectra PACS which consists of Sectra Workstation (K081469) and Sectra Core (identified as a Class I exempt by the FDA in 2000).

The Sectra Pathology Import Server (SPIS) is used for importing digital pathology images (scanned slides) from the scanner. These images are viewed and manipulated by end users in the Pathology Image Window which is displayed on the Sectra Workstation IDS7 (using the Dell MR2416 monitor).

The subject device is typically operated as follows:

1. The subject device receives quality-controlled images from the scanner and extracts a copy of the images' metadata. The unaltered images are then sent to the external image storage. A copy of the image metadata (e.g. the pixel size) is stored locally in the subject device to increase the operational performance (e.g. response times) of the subject device.
2. The reading pathologist selects a case (patient) from a worklist external to the subject device whereby the subject device fetches the associated images from the external image storage.
3. The reading pathologist uses the subject device to view and interpret the images:
    a. The pathologist can adjust zoom and pan the image at will.
    b. The pathologist can adjust focus (when different focus depths are available).
    c. The pathologist can measure distances and areas in the image.
    d. The pathologist can annotate images.
    e. The pathologist can choose to view multiple images side by side in a synchronized fashion.
4. The above steps are repeated as required.

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

Indications for Use/Intended Use:

For In Vitro Diagnostic Use
Sectra Digital Pathology Module device is a software 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 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. Sectra Digital Pathology Module is intended for use with Leica's Aperio AT2 DX scanner and Dell MR2416 monitor.

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Summary of Technological Characteristics:

Item	Subject Device	Predicate
Indications for Use	For In Vitro Diagnostic Use Sectra Digital Pathology Module device is a software 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 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. Sectra Digital Pathology Module is intended for use with Leica's Aperio AT2 DX scanner and Dell MR2416 monitor.	The Aperio AT2 DX System is an automated digital slide creation and viewing system. The Aperio AT2 DX 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 Aperio AT2 DX System is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. The Aperio AT2 DX System is composed of the Aperio AT2 DX scanner, the ImageScope DX review application and Display. The Aperio AT2 DX 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 the Aperio AT2 DX System.
Specimen type	Surgical pathology slides prepared from FFPE tissue	Surgical pathology slides prepared from FFPE tissue

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Item	Subject Device	Predicate
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)	Aperio ImageScope DX
Scanner	Sectra Digital Pathology Module does not include a scanner, however, it is indicated for use with the Aperio AT2 DX	Aperio AT2 DX
Display monitor	Sectra Digital Pathology Module does not include a monitor, however, it is indicated for use with the Dell MR2416	Dell MR2416

Performance data	**Description**
Color reproducibility	Pixel-wise comparison towards Aperio ImageScopeDX has been performed including zooming and panning operations across

	multiple tiles. Sectra Digital Pathology Module has been found to reproduce colors adequately with respect to its intended use.
Turnaround time	Provided that the system requirements are fulfilled: - When selecting a case, it should not take longer than 7 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.
Measurements	Measurement accuracy has been verified using a test image containing objects with known sizes.
Human factors testing	Sectra Digital Pathology Module has been found to be safe and effective for the intended users, uses, and use environments.

Substantial Equivalence Comparison:

The major difference between the subject and predicate device is that the predicate device includes the Aperio AT2 DX scanner and the Dell MR 2416 Monitor, whereas the subject device is indicated for use with the same scanner and monitor. Therefore, the indications for use are slightly different in that the Aperio AT2 DX System Indication for use includes a section regarding the creation of digital images and the Sectra Digital Pathology Module is only focused on viewing those digital images.

The proposed Sectra Digital Pathology Module when used with the Aperio AT2 DX scanner and Dell MR2416 has similar Indications for Use, Functional, and Technological Characteristics as the ImageScope DX viewer application software of the predicate device and is therefore substantially equivalent to the Aperio predicate device (K190332).

Summary of Studies:

Non-clinical test results:

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

Color Reproducibility Testing demonstrated that the color reproducibility in Sectra Pathology Image Window was non-inferior to the color reproducibility in ImageScopeDX and that the Sectra Digital Pathology Module reproduced colors adequately with respect to its intended use.

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.

Conducted per FDA's Guidance on Applying Human Factors and Usability Engineering to Medical Devices:

Task-based usability tests showed the Sectra Digital Pathology Module user interface to be intuitive, safe, and effective for the range of intended users.

Clinical tests results:

Substantial equivalence determination is not based upon clinical study results.

Conclusion:

The proposed Sectra Digital Pathology Module when used with the Aperio AT2 DX scanner and Dell MR2416 has similar Indications for Use, Functional, and Technological Characteristics as the ImageScope DX viewer application software of the predicate device. The results of non-clinical testing demonstrate the device is safe and effective and substantially equivalent to the Aperio predicate device (K190332).

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