Tribun Health
Françoise Veyriac
QARA & Clinical Affairs Director
30 Boulevard de Vaugirard
Paris, 75015
France

May 14, 2025

Re: K250414
Trade/Device Name: CaloPix
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Class: Class II
Product Code: QKQ
Dated: February 13, 2025
Received: February 13, 2025

Dear Françoise Veyriac:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250414

Device Name
CaloPix

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

CaloPix is a software only device for viewing and management of digital images of scanned surgical pathology slides prepared from Formalin-Fixed Paraffin Embedded (FFPE) tissue.
CaloPix is intended for in vitro diagnostic use as an aid to the pathologist to review, interpret and manage these digital slide images for the purpose of primary diagnosis.
CaloPix 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 CaloPix.

CaloPix is intended to be used with the interoperable components specified in the below Table:

Scanner Hardware	Scanner Output File Format	Interoperable Displays
Leica Aperio GT 450 DX scanner	SVS	Dell U3223QE
Hamamatsu NanoZoomer S360MD Slide scanner	NDPI	JVC Kenwood JD-C240BN01A

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

CaloPix

Date of Summary: May 14, 2025

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Identification of the Subject Device

Trade/Device name:	CaloPix
Version:	6.1.0 IVDUS
Regulation number:	21 CFR 864.3700
Classification name:	Whole Slide Imaging System
Device Classification:	Class II
Product code:	QKQ
Review Panel:	88 – Pathology
Common name:	Digital Pathology Image Viewing and Management Software
510 (k) Number:	K250414

Identification of the Predicates Devices

Trade/Device name	NanoZoomer S360MD Slide scanner system	Aperio GT 450 DX
510(k) number:	K213883	K232202
Clearance date	September 27, 2022	April 16, 2024
Regulation number:	21 CFR 864.3700	
Classification name	Whole slide Imaging System	
Device Classification	Class II	
Product code:	PSY	
Review Panel:	88 - Pathology	
Common name	Digital Pathology Whole Slide Imaging System	

Indications for Use/Intended Use of the device

For In Vitro Diagnostic Use Only

CaloPix is a software only device for viewing and management of digital images of scanned surgical pathology slides prepared from Formalin-Fixed Paraffin Embedded (FFPE) tissue.

CaloPix is intended for in vitro diagnostic use as an aid to the pathologist to review, interpret and manage these digital slide images for the purpose of primary diagnosis. CaloPix 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 CaloPix.

CaloPix is intended to be used with the interoperable components specified in the below Table.

Scanner Hardware	Scanner Output File Format	Interoperable Displays
Leica Aperio GT 450 DX scanner	SVS	Dell U3223QE
Hamamatsu NanoZoomer S360MD Slide scanner	NDPI	JVC Kenwood JD-C240BN01A

Description of the Device

CaloPix, version 6.1.0 IVDUS, is a web-based software-only device that is intended to aid pathology professionals in viewing, interpreting and managing digital Whole Slide Images (WSI) of glass slides obtained from the Hamamatsu NanoZoomer S360MD slide scanner (NDPI file format) and viewed on the JVC Kenwood JD-C240BN01A display, as well as those obtained from the Leica Aperio GT 450 DX scanner (SVS file format) and viewed on the Dell U3223QE display.

CaloPix does not include any automated Image Analysis Applications that would constitute computer aided detection or diagnosis.
CaloPix is for viewing digital images of scanned glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy.

As a whole, CaloPix is a pathology Image Management System (IMS) which brings case-centric digital pathology image management, collaboration, and image processing. CaloPix consists of:

- Integration with Laboratory Information Systems (LIS): Allows to obtain automatically from the LIS patient data associated with the cases, scanned whole slide images and other related medical images to be analyzed. The data stored in the database is automatically updated according to the interface protocol with the LIS.

  DataBase: After ingestion, scanned WSI can be organized in the CaloPix database consisting of folders (cases) containing patient identification data and examination results from a LIS.

  Ingestion of the slides is performed through an integrated module that allows their automatic indexation based on patient data retrieved from the LIS. After their ingestion,

image files are stored in a CaloPix-specific file storage environment, that can be on premises or in the cloud.

- The **CaloPix viewer** component to process scanned whole slide images, that includes functions for panning, zooming, screen capture, annotations, distance and surface measurement, and image registration. This viewer relies on image servers (IMGSRV) which extract image tiles from the whole slide image file and send these tiles to the CaloPix viewer for smooth and fast viewing.

CaloPix operates as follows:

1. After the WSI image is acquired using one of the intended scanners, in accordance with the WSI scanner Instructional Manual and any additional standard laboratory procedures, the WSI becomes available in the scanner's file system. The WSI is then sent to end-user-provided image storage attached to the local network. (not part of the subject device).

   The WSI is then ingested into the CaloPix database at which point the CaloPix workflow is initiated.
2. The reading pathologist selects a case from a worklist within CaloPix, whereby CaloPix fetches the associated images from the image storage.
3. The image quality and other image data must be manually evaluated in the CaloPix viewer by the pathologist, and deemed acceptable, prior to using a whole slide image for diagnosis.
4. The reading pathologist uses the **CaloPix viewer** to view and interpret the images using the following functionalities:
   - Continuous zooming and panning;
   - Measuring distances;
   - Creating annotations during review using manual annotation tools and manual counting tools;
   - Viewing and comparing multiple slide images simultaneously in multiple windows;
   - Tracking of visited areas and annotations and digital bookmarks.
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. Upon conclusion of using the system, the pathologist clicks "Sign Out" in the user menu.

CaloPix is designed to be deployed to a customer-managed infrastructure or in a cloud infrastructure and may be accessed on the user's workstation browser. CaloPix operates with and is validated for use with the components specified in the tables below.

Table 1: Interoperable Components for Use with CaloPix

Manufacturer	Model
Hamamatsu Photonics K.K.	Scanner: NanoZoomer S360MD Slide scanner Display: JVC Kenwood JD-C240BN01A
Leica Biosystems Imaging, Inc.	Scanner: Aperio GT 450 DX scanner Display: Dell U3223QE

Table 2: Computer environment / System requirements

Environment	Component	Minimum Requirements
Hardware	Computer	PC computer
	Processor	Minimum: Intel® Core™ i5 / AMD Ryzen 5 Recommended: Intel® Core™ i7 / AMD Ryzen 7
	Graphics card	Nvidia GeForce RTX 2060 / AMD Radeon RX 480
	Memory	Minimum: 4GB / Recommended: 8GB
	Network connectivity	10 Mbit/s between the client and the server
	Keyboard / Mouse / Trackpad	Standards keyboard and mouse supported by Windows 10 and higher versions Optional: 3D SpaceMouse Wireless, 3D SpaceMouse Pro from 3D connection
Software	Operating system	Windows 10 or higher
	Supported browsers	Google Chrome (version 91 and above) Microsoft Edge (version 106 and above)

Summary of Performance Testing

A series of tests were performed to assess the safety and effectiveness of CaloPix. All the test results demonstrate that the subject device meets the requirements of its pre-defined acceptance criteria and intended use.

The following performance tests were conducted per FDA guidance "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Device (2016)" and "Applying Human Factors and Usability Engineering to Medical Devices (2016)".

<table>
<tr><th>Test</th><th>Result</th></tr>
<tr><td>Pixel-wise comparison</td><td>Pixel-wise comparison testing was conducted to compare images reproduced by CaloPix and the comparators (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") as described below for the same image file format generated from the same intended use scanner to validate identical image reproduction on the same intended displays.
<table>
<tr><th>Scanner</th><th>Image File Format</th><th>Subject Device</th><th>Comparator (Predicate device IRMS)</th><th>Displays</th></tr>
<tr><td rowspan="2">Hamamatsu NanoZoomer S360MD Slide scanner</td><td rowspan="2">NDPI</td><td>CaloPix /Chrome</td><td>NZViewMD</td><td rowspan="2">Display JVC Kenwood JD-C240BN01A</td></tr>
<tr><td>CaloPix /Edge</td><td>NZViewMD</td></tr>
<tr><td rowspan="2">Leica Aperio GT450DX scanner</td><td rowspan="2">SVS</td><td>CaloPix /Chrome</td><td>Aperio WebViewer DX/Chrome</td><td rowspan="2">Display Dell U3223QE</td></tr>
<tr><td>CaloPix /Edge</td><td>Aperio WebViewer DX/Chrome</td></tr>
</table>
A total of 25 H&E-stained and 5 IHC-stained (Masson's trichrome stain, CD8, CD3, or CD20), formalin-fixed paraffin-embedded (FFPE) tissue glass slides, were scanned using both slide scanner systems. The slides scanned with the Leica Aperio GT450 DX scanner were saved in SVS format, while the slides scanned with the Hamamatsu NanoZoomer S360MD Slide Scanner were saved in NDPI format. For each WSI, 3 regions of interest (ROIs) were identified to highlight relevant pathological features, as verified by a pathologist.
Screenshots of these ROIs were captured at two magnification levels (20x and 40x) across multiple displays and browsers as specified in the above table. The testing process ensured comprehensive evaluation across display variations, with all image pairs registered and cropped for analysis. Every pixel of each screenshot was sampled to calculate the pixel-wise color difference using the CIEDE2000 (ΔE00) metric.</td></tr>
</table>

	The acceptance criterion for this testing required that the 95th percentile of the pixel-wise color differences in any image pair between CaloPix and the predicate device IRMS must be less than 3 CIEDE2000 (i.e., < 3 ΔE_{00}) to be considered as acceptable. Tests results showed that the 95th percentile of pixelwise differences between CaloPix and the comparators were less than 3 CIEDE2000, indicating that their output images can be considered to be pixel-wise identical. Therefore, it was determined that color images reproduced by CaloPix were visually adequate with respect to its intended use.
Measurements of area and distance	Measurements accuracy has been verified by comparing the measurements of markings made in CaloPix viewer to the measurements of markings made in NZViewMD viewer, for the same Regions of Interest on slides. These measurement checks were also carried out between the CaloPix viewer and the Aperio WebViewer DX. These tests were used to validate the measurement accuracy of the subject device. Tests verified that the distance and area measurements made in the CaloPix viewer accurately reflected the distance and area measurements made in the NZViewMD viewer, as well as the distance and area measurements made in the Aperio WebViewer DX viewer. These results show that CaloPix performed accurate measurements with respect to its intended use.
Turnaround time	The system requirements have been fulfilled: - When selecting an image, it should not take longer than 10 seconds until the image is fully loaded. - When panning the image, it shall not take longer than 7 seconds until the image is fully loaded. - When zooming the image, it shall not take longer than 7 seconds until the image is fully loaded. Turnaround times for opening an image and panning or zooming have been determined and found to be adequate for the intended use of the subject device.

Human Factors validation study	The usability test was conducted per FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices (2016)". CaloPix has been found to be safe and effective for the intended users, uses and use environments.

Substantial Equivalence Determination

The proposed subject device has the same Indications for Use and similar functional and technological as the Image Management Software (IMS) application software for predicate devices and is therefore substantially equivalent to the predicate's devices.

Item	Subject device	Predicate device (K213883)	Predicate device (K232202)
Device trade Name	CaloPix	NanoZoomer S360MD Slide scanner system	Aperio GT 450 DX
Product code	QKQ	PSY	PSY
Regulation	21 CFR 864.3700	21 CFR 864.3700	21 CFR 864.3700
Regulation name	Whole Slide Imaging System	Whole Slide Imaging System	Whole Slide Imaging System
Classification	II	II	II
General Device Characteristics Similarities			
Intended Use / Indications for Use	For In Vitro Diagnostic Use CaloPix is a software-only device for viewing and management of digital images of scanned surgical pathology slides prepared from Formalin-Fixed Paraffin Embedded (FFPE) tissue. CaloPix is intended for in vitro diagnostic use as an aid to the pathologist to review, interpret and manage these digital slide images for the purpose of primary diagnosis.	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 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 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

<table>
<tr><th>Item</th><th>Subject device</th><th>Predicate device (K213883)</th><th>Predicate device (K232202)</th></tr>
<tr>
<td>Intended Use / Indications for Use</td>
<td>CaloPix is not intended for use with frozen sections, cytology, or non-FFPE hematopathology specimens.

CaloPix is intended to be used with the interoperable components specified in the below table:
<table>
<tr><th>Scanner Hardware</th><th>Image File Format</th><th>Interoperable Displays</th></tr>
<tr><td>Hamamatsu NanoZoomer S360MD Slide scanner</td><td>NDPI</td><td>JVC Kenwood JD-C240BN01A</td></tr>
<tr><td>Leica Aperio GT 450 DX scanner</td><td>SVS</td><td>Dell U3223QE</td></tr>
</table>
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 CaloPix.</td>
<td>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.</td>
<td>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 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 450DX.</td>
</tr>
</table>

Item	Subject device	Predicate device (K213883)	Predicate device (K232202)
Principle of Operation	After the WSIs are acquired by using the NanoZoomer S360MD Slide scanner or the Leica Aperio GT 450 DX scanner, the WSI are stored in customer provided image storage. During image review, the pathologist opens the WSI (in NDPI or SVS format, depending on the scanner used for digitization) from the image storage using CaloPix; performs further QC and then reads the WSI to make a diagnosis	The NanoZoomer System is a WSI system. The system's embedded image processing software is responsible for image acquisition and the processing of individual tiles prior to image composition or stitching. The NZAcquireMD software organizes all WSI tiles into a single NDPI file, which is a proprietary file format. WSI are automatically saved to the hard disk during scanning and may be viewed later by using the included viewing software. During the review, the pathologist opens WSI from the image storage attached to the local network, performs further QC and reads WSI of the slides to make a diagnosis.	The Aperio GT 450 DX is a WSI system. The technician places the slides into the Aperio GT 450 DX scanner. The scanner automatically loads the slides, takes the micro images, finds the tissues, and scans the slides. The scanner also automatically performs quality control (QC) and notifies the user of any image quality issue during the image acquisition. The image data is sent to end-user-provided image storage attached to the local network. During the 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.
Specimen Type	Surgical pathology slides prepared from FFPE tissue	Same	Same
Item	**Subject device**	**Predicate device (K213883)**	**Predicate device (K232202)**
Image storage	Images are stored in the end-user-provided image storage attached to the local network or in the cloud.	Images are stored in the end-user-provided image storage attached to the local network	Images are stored in the end-user-provided image storage attached to the local network.
Type of Software Application	Web-based application	Windows based	Same
User interface	CaloPix	NZViewMD	Aperio WebViewer DX

General Device Characteristics Differences			
Device Components	Image Management Software (IMS)	Scanner, IMS and Display	Scanner, IMS and Display
Diagnostic Image File Formats	Hamamatsu NDPI. Leica SVS.	Hamamatsu NDPI.	Leica SVS and DICOM.
Image Manipulation Functions	Panning, zooming, image adjustments, annotations, distance/area measurements and manual counting.	Panning, zooming, image adjustments, annotations, distance/area measurements.	Panning, zooming, gamma functions, annotations, and measurements (distance).

CONCLUSION

Based on the information provided in the 510 (k), the subject device CaloPix is substantially equivalent to the previously cleared predicates devices, when used with the Hamamatsu NanoZoomer S360MD slide scanner and the JVC Kenwood JD-C240BN01A monitor or the Leica Aperio GT 450 DX scanner and the Dell U3223QE monitor.