PathAI, Inc
Katy Wack
VP, Clinical Development & Regulatory Affairs
PathAI, Inc.
1325 Boylston Street
Suite 10000,
Boston, MA 02215

September 1, 2022

Re: K212361
Trade/Device Name: Novo
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: QKQ

Dear Katy Wack:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 11, 2022. Specifically, FDA is updating this SE letter for errors in the applicant and the correspondent name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shyam Kalavar, OHT7: Office of In Vitro Diagnostics, Phone: 301-796-6807, Email: shyam.kalavar@fda.hhs.gov.

Sincerely,

Shyam Kalavar -S

Shyam Kalavar
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

PathAI, LLC
Katy Wack, Ph.D.
VP, Clinical Development & Regulatory Affairs
120 Brookline Avenue
Boston, Massachusetts 02215

August 11, 2022

Re: K212361
Trade/Device Name: Novo
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Class: Class II
Product Code: QKQ
Dated: July 28, 2021
Received: July 30, 2021

Dear Katy Wack:

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,

Shyam Kalavar -S
2022.08.11 16:53:55 -04'00'

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

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)*
K212361

Device Name
Novo

Indications for Use *(Describe)*
Novo is a software only device intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret, and manage digital images of these slides for primary diagnosis. Novo 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, where necessary, use conventional light microscopy review when making a diagnostic decision. Novo is intended for use with the Philips Ultra Fast Scanner and the Barco PP27QHD or Philips PS27QHDCR display.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Novo

Date Prepared: August 11, 2022

Submitter

PathAI, Inc.
1325 Boylston Street Suite 10000
Boston, MA 02215

Contact Person

Katy Wack
Phone: (617) 500-8457

DEVICE

Proprietary Name:	Novo
Common Name:	The PathAI Novo Viewer
Classification Name:	Whole Slide Imaging System
Regulation Section:	21 CFR 864.3700
Regulatory Classification:	Class II
Product Code:	QKQ
Review Panel:	88 - Pathology

PREDICATE DEVICE

Proprietary Name:	Philips IntelliSite Pathology Solution (PIPS)
Submission Number:	DEN160056

DEVICE DESCRIPTION

The PathAI Novo device is a web-based software-only device that is intended to aid pathology professionals in the viewing, interpretation, and management of digital whole slide images (WSIs) of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue using the Philips IntelliSite Pathology Solution (PIPS) Ultra Fast Scanner (UFS).

The proposed device is typically operated as follows:

1. A user prepares and scans slides and reviews the slide quality in accordance with the PIPS UFS IFU and standard lab procedures. The Novo device workflow is initiated when a user uploads WSIs from the local file system to the cloud storage using Novo.

2. After uploading WSIs to cloud storage using Novo, a user builds a patient accession using the patient's medical record number (MRN), date of birth (DOB) and accession ID to support linkage of one or more slides from a single procedure using patient identifiers in Novo.

3. A pathologist uses the slide viewer to perform their primary diagnosis workflow including zooming and panning images.

After viewing all images belonging to a particular accession, the pathologist will make a diagnosis.

Novo operates with the following components:

Table 1: WSI scanner

Manufacturer	**Model**
Philips Medical Systems Nederland B.V.	Ultra Fast Scanner (UFS)

Table 2: WSI displays

Manufacturer	**Model**
Barco N.V.	PP27QHD
Philips	PS27QHDCR

Table 3: Computer environment/ System Requirements

System	**Details**
Computer System	RAM: 4.0 GB Display Calibration tool: MediCal QAWeb Agent for Philips and Barco Displays
Display	Barco (PP27QHD) or Philips (PS27QHDCR) Pixel resolution: 2560w x 1440h Panel type: Color LCD Technology: IPS technology with a-Si Thin Film Transistor Physical size: 648.5 mm x 423 mm x 91.3 mm (with backlight disc)
Web Browser	Google Chrome 81.0 or later
Network	Internet access Outbound traffic enabled to port 443 25 Mbps download and upload speed

INDICATIONS FOR USE/INTENDED USE

Novo is a software only device intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret, and manage digital images of pathology slides for primary diagnosis. Novo 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, where necessary, use conventional light microscopy review when making a diagnostic decision. Novo is intended for use with the Philips Ultra Fast Scanner and the Barco PP27QHD or Philips PS27QHDCR display.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The following table summarizes the similarities and differences between the PathAI device and the predicate device, Philips IntelliSite Pathology Solution (PIPS).

Attribute	**Predicate Device**	**Proposed PathAI Device**
Device Trade Name	Philips IntelliSite Pathology Solution (PIPS) (DEN160056)	Novo
Intended Use/Indications for Use	The Philips IntelliSite Pathology Solution (PIPS) is an automated digital slide creation, viewing, and management system. The PIPS 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 PIPS is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. The PIPS comprises the Image Management System (IMS), the Ultra Fast Scanner (UFS) and Display. The PIPS 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 PIPS.	Novo is a software only device intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret, and manage digital images of pathology slides for primary diagnosis. Novo 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, where necessary, use conventional light microscopy review when making a diagnostic decision. Novo is intended for use with the Philips Ultra Fast Scanner and the Barco PP27QHD or Philips PS27QHDCR display.
Product Code	PSY	QKQ

Specimen Type	Surgical pathology H&E slides prepared from FFPE tissue	Same
Image File Format	Philips UFS iSyntax File	Philips UFS iSyntax File converted to device specific image format
Image Manipulation Functions	Panning, zooming, color manipulation function, annotations, and measurements (distance & area)	Panning, zooming, notes
Type of Software Application	Internet Browser Based	Same
Device Components	Ultra Fast Scanner (UFS), Image Management System (IMS), Display	Image viewing Software (Novo)
Principle of Operation	After WSI images are successfully acquired by using PIPS UFS, the WSI images are stored in IMS Application Server & Storage software that is not provided as part of the PIPS, but may be located in a central server room separate from the workstation with the IMS viewing software and Display. During review, the pathologist opens WSI images from IMS Server & Storage, perform further QC and reads WSI images of the slides to make a diagnosis.	After WSI images are successfully acquired by using PIPS UFS, the WSI images are stored in the cloud. During review, the pathologist opens WSI images from storage (displayed as DZI images), performs further QC and reads WSI images of the slides to make a diagnosis.
Image Storage	Images are stored in an end user provided image storage (PIPS IMS Application Server & Storage) attached to the local network	Images are stored in the cloud
End User's Interface	PIPS Image Management System (IMS)	Novo

Substantial Equivalence Comparison

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

PERFORMANCE DATA

Performance data	Description
Pixel-wise comparison	A pixel-wise comparison test was performed to compare images which were reproduced by Novo and the Philips IntelliSite Pathology Solution Image Management System (PIPS/IMS) for the same iSyntax file to demonstrate identical image reproduction. Test results show that the color differences (ΔE_{00}) between Novo and PIPS/IMS are not zero. Further, testing was conducted to compare Novo-generated images with JPEG-compressed PIPS/IMS-generated images. Test

	results show that the Novo-generated images are similar to PIPS/IMS-generated images that had been JPEG-compressed at quality 95. Based on the findings from bench testing, an additional clinical study was performed to establish the safety and effectiveness of the device
Clinical Study	A clinical study was conducted to demonstrate that viewing, reviewing, and diagnosing WSIs of H&E stained FFPE tissue slides using Novo [manual digital read (MD)] is non-inferior to glass slide reads using optical (light) microscopy [manual optical (MO)]. The primary endpoint of the study was the difference in major discordance rates between MD and MO when compared to the reference (main) diagnosis, which was the original sign-out pathologic diagnosis using MO [ground truth, (GT)] rendered at the institution. The differences in major discordance rates between MD and GT compared to MO and GT were -0.1% (95% CI, -2.05, 1.78) for all organs. The upper limit of the CI for the major discordance rate was 1.78%, which is less than the prespecified noninferiority threshold of 4%, therefore meeting the primary objective of the study.
Turnaround time	The system requirements have been fulfilled: • Images load in less than 7 seconds when selected for viewing • Images load in less than 10 seconds when panning or zooming
Human factors testing	Novo has been found to be safe and effective for the intended users, uses, and use environments.

CONCLUSION

Based on the information provided in this 510(k), the proposed PathAI device is substantially equivalent to the previously cleared predicate, when used with the PIPS UFS and Barco PP27QHD or Philips PS27QHDCR display. Please note that a clinical study was conducted to establish the Substantial Equivalence of the device.