510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K233126

B Applicant

Due to an administrative error, the applicant's name was previously stated as "AetherAI Co., Ltd" and is now corrected.

aetherAI Co., Ltd.

C Proprietary and Established Names

aetherSlide

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QKQ	Class II	21 CFR 864.3700 - Whole Slide Imaging System	PA - Pathology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Type of Test:

Software only device

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

B Indication(s) for Use:

For In Vitro Diagnostic Use

aetherSlide is a software-only device intended for viewing and managing 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. aetherSlide 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 quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. aetherSlide is intended for use with the Philips Ultra Fast Scanner (UFS) and the Philips PS27QHDCR monitor.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

aetherSlide, version 101692 is a web-based, software only device that is intended to aid pathology professionals in viewing, interpretation and management of digital whole slide images (WSI) of scanned surgical pathology slides prepared from formalin-fixed paraffin-embedded (FFPE) tissue obtained from Philips Ultra Fast Scanner (UFS). It aids the pathologist in the review, interpretation, and management of pathology slide digital images used to generate a primary diagnosis.

aetherSlide is operated as follows:

1. Image acquisition is performed using the Philips UFS. The operator conducts quality control of the digital slides according to Philips UFS instructions and laboratory specifications to determine if re-scans are necessary.
2. Once the WSI is acquired using Philips UFS, it becomes available in the Philips IntelliSite Pathology Solution (PIPS) database file systems. The operator then exports the WSI in iSyntax format from PIPS Image Management System (IMS) to a designated storage path.
3. The operator can manually upload the exported WSI into aetherSlide via aetherSlide Gateway, which is a separate medical image communications software. Alternatively, the aetherSlide Gateway can automatically initiate the upload of the WSI into aetherSlide when the auto-upload function is activated on the settings page of aetherSlide Gateway. Once the WSI is uploaded, the reading pathologist uses the device to perform the following actions:
    - View slide image
    - Zoom and pan the image
    - Measure distances in the image
    - Annotate the image

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

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

Table 1. Interoperable Components for Use with aetherSlide

Components	Manufacturer	Model
Scanner	Philips Medical Systems Nederland B.V.	Ultra Fast Scanner
Display	Philips Medical Systems Nederland B.V.	PS27QHDCR Monitor

Table 2. Computer Environment/System Requirements

Environment	Component	Minimum Requirements
Client PC		
Hardware	Processor	Intel or AMD with 64-bit support, at least 2 GHz, at least 2 cores
	Memory	4 GB RAM or higher
	Storage	128 GB SSD or higher
	Network	100 Mbps Ethernet or above
Software	Operating System	Microsoft Windows 11
	Browser	Google Chrome (122 or higher)
Gateway Workstation		
Hardware	Processor	Intel or AMD with 64-bit support, at least 2 GHz, at least 2 cores
	Memory	4 GB RAM or higher
	Storage	128 GB SSD or higher
	Network	100 Mbps Ethernet or above
Software	Operating System	Microsoft Windows 11
Server		
Hardware	Processor	Intel or AMD with 64-bit support, at least 2 GHz, at least 8 cores
	Memory	16 GB RAM or higher
	Storage	512 GB SSD or higher
	Network	1 Gbps or above
Software	Operating System	Ubuntu 22.04 LTS

B Instrument Description Information:

1. Instrument Name:
   aetherSlide

2. Specimen Identification:

aetherSlide uses digital images of scanned surgical pathology slides of human samples prepared from formalin-fixed paraffin embedded (FFPE) tissue. The reading pathologist selects a case (patient) from a worklist whereby the subject device fetches the associated images from the image storage. The scanned images are identified based on the previously assigned specimen identifier.

3. Specimen Sampling and Handling:
   Specimen sampling and handling are performed upstream and independent of the use of the subject device. Specimen sampling includes biopsy or resection specimens which are processed using histology techniques. The FFPE tissue section is H&E stained. Digital images are then obtained from these glass slides using the PIPS Ultra Fast Scanner.

4. Calibration:
   Not applicable

5. Quality Control:
   Prior to using a whole slide image for diagnosis, the operator shall conduct quality control of the digital slides according to Philips UFS instructions and any additional laboratory specifications. This process ensures the acceptability of image quality for all scanned slide images and determines if re-scans are necessary.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Philips IntelliSite Pathology Solution

B Predicate 510(k) Number(s):

DEN160056

C Comparison with Predicate(s):

Device & Predicate Device(s):	K233126	DEN160056
Device Trade Name	aetherSlide	Philips IntelliSite Pathology Solution (PIPS)
General Device Characteristic Similarities		
Intended Use/Indications For Use	For In Vitro Diagnostic Use aetherSlide is a software-only device intended for viewing and managing digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to	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

	review, interpret, and manage digital images of pathology slides for primary diagnosis. aetherSlide 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 quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. aetherSlide is intended for use with the Philips Ultra Fast Scanner (UFS) and the Philips PS27QHDCR monitor.	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.
Specimen Type	Digitized surgical pathology slides prepared from FFPE tissue	Same
Diagnostic Image File Format	iSyntax	Same
Type of Software Application	Internet browser-based application	Same
Principle of Operation	After WSI images are successfully acquired by using PIPS UFS, the WSI images are stored in the image storage provided by the end user. During review, the pathologist opens WSI images from storage, performs 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 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.
Image Storage	Images are stored in an end user provided image storage attached to the local network.	Images are stored in the end user provided image storage (PIPS IMS Application Server & Storage) attached to the local network.
Image Manipulation	Panning, zooming, color manipulation function,	Panning, zooming, color manipulation function, annotations,

and Review Functions	annotations, and measurements (only for distance)	and measurements (distance & area)
General Device Characteristic Differences		
Device Components	aetherSlide imaging viewing software, aetherSlide Gateway	Ultra Fast Scanner (UFS), Image Management System (IMS), Display
End User's Interface	aetherSlide	PIPS IMS

VI Standards/Guidance Documents Referenced:

1. FDA Guidance for Industry "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices", April 20, 2016.
2. FDA Guidance for the Applying Human Factors and Usability Engineering to Medical Devices (2016)
3. FDA Guidance for the Content of Premarket Submissions for Device Software Functions (2023)
4. ISO 14971:2019, Medical devices - Application of risk management to medical devices
5. ISO/TR 24971:2020, Medical devices — Guidance on the application of ISO 14971
6. ISO 13485:2016, Medical devices — Quality management systems — Requirements for regulatory purposes
7. IEC 62304:2006/Amd:2015, medical device software — Software life cycle processes — Amendment 1
8. FDA Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (2014)
9. ISO 14971:2019, Medical devices - Application of risk management to medical devices
10. NIST Special Publication 800-115, Technical Guide to Information Security Testing and Assessment

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   Not applicable

2. Linearity:
   Not applicable

3. Analytical Specificity/Interference:
   Not applicable

4. Accuracy (Instrument):
   Not applicable

5. Carry-Over:
   Not applicable

B Other Supportive Instrument Performance Characteristics Data:

Technical performance testing was conducted with aetherSlide. The subject device was compared to the predicate device's image review manipulation software (IRMS, as defined in FDA guidance document, "Guidance for Industry – Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices," dated April 20, 2016) using the quantitative pixel-wise comparison method. The basis for the comparison was the CIEDE2000 color difference equation, ΔE.

1. Bench Testing - Pixelwise comparison test

Pixel-wise comparison testing to demonstrate identical image reproduction was conducted to compare WSIs reproduced by the subject device and PIPS IMS. The devices were tested as operating with the intended components, including the scanner (PIPS UFS), image management system (PIPS IMS, aetherSlide with Google Chrome,) and display (PS27QHDCR).

The device was tested with multiple slides across multiple regions of interest (ROI) at multiple magnification levels. A total of 30 H&E-stained, FFPE glass slides of normal and tumor tissues from various human anatomical organs were used in the testing. The glass slides were scanned on a PIPS UFS to obtain 30 WSIs. For each of the 30 WSIs, 3 ROIs from different locations were selected by qualified personnel to represent various features in the tissue samples. Each ROI was captured at 4 magnification levels (5x, 10x, 20x, 40x).

The screenshots were captured from the intended display while viewing with the subject device and predicate PIPS IMS. The screenshots were cropped and registered to be pixelwise comparable. The cropped image included most of the pixels in the image except for those in the viewer-specific user interface areas.

Two sets of images were collected: PIPS IMS and aetherSlide using Google Chrome. Each image set included 360 images that covered all combinations of 30 slides, 3 ROIs and 4 magnification levels. The testing data, including the overview images of the 30 glass slides with annotations of the ROIs, registration/cropping information, and captured images, were provided in the FDA specific format.

The PIPS image set was used as the reference to compare the aetherSlide image set to determine whether all the 360 image-pairs were identical. Two images are considered identical if the 95th percentile of the pixelwise differences, computed using the International Commission on Illumination (CIE) color difference metric CIEDE2000 (ΔE00), is less than 3 ΔE00. Testing results showed that the pixelwise differences across all 360 image-pairs were less than 3 ΔE00. The mean 95th percentile ΔE00 value was 0.16 with the lowest value reported as 0.00 and the highest reported as 0.71. Testing results demonstrated that WSIs reproduced by aetherSlide are identical to images reproduced by the predicate device.

2. Turnaround Time

The turnaround time for opening an image and panning were measured in the subject device when using Google Chrome over different magnifications levels and over multiple fields of view (FOVs). The test results show that:

- When selecting a case, the average duration time until the image was fully loaded was 4.31 seconds.
- When panning the images (one quarter of the monitor), the average panning time was 1.05 seconds, 0.85 seconds, 0.99 seconds and 0.78 seconds at magnification levels of 4x, 10x, 20x, and 40x respectively.

The subject device has been found to have an acceptable turnaround time with respect to its intended use for opening and panning the image.

3. Measurements

Measurement accuracy testing was performed using the scanned image of a grid micrometer. The scanned image of a grid micrometer (R1L3S3P, Positive Grid Distortion Target, ThorLabs) was used as the test target to verify the length measurement accuracy of the subject device. The 100 µm grid with horizontal and vertical spacing of 0.1 mm was used in the testing. The task of the human tester was to use the subject device's measurement tool to measure 0.1 mm (1 cell) and 0.2 mm (2 cells), both horizontally and vertically, at 5x, 10x, 20x, and 40x magnifications. Each measurement was conducted three times and the average was reported. Results showed that all measurement values obtained by the human tester using the measurement tool were also 0.1 mm or 0.2 mm for each of the specified measurements above. Test results demonstrated that the subject device performed accurate measurements with respect to its intended use.

4. Human Factor (Usability) testing

The aetherSlide device Human Factors (HF) validation test was conducted to demonstrate that the device can be used by the intended users without serious use errors or problems, for the intended uses and under the expected use conditions. The HF validation test was performed by representative users and conducted per FDA's Guidance on Applying Human Factors and Usability Engineering to Medical Devices (2016). A systematic evaluation of task-based usability including critical tasks required for operation of the device were evaluated at multiple sites using multiple users. All tasks associated with reviewing and reporting results for cases including confirmation that all slides belonging to specific cases are reviewed before reporting results, were included in the HF validation test. Overall, the results of the human factors testing were acceptable. The aetherSlide device has been found to be safe and effective for intended users, users and use environments.

VIII Proposed Labeling:

The labeling supports or the finding of substantial equivalence for this device.

IX Conclusion:

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