AetherAI Co., Ltd.
Leticia Hong
Team Leader of RA
15F & 15F-1., No. 508, Sec. 7
Zhongxiao E. Rd., Nangang Dist.
Taipei City, 115011
Taiwan

May 30, 2024

Re: K233126
Trade/Device Name: aetherSlide
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: QKQ
Dated: September 15, 2023
Received: September 27, 2023

Dear Leticia Hong:

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
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)*
K233126

Device Name
aetherSlide

Indications for Use *(Describe)*
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.

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

1. Date of Summary: 05/30/2024

2. Submitter: aetherAI Co., Ltd.

Address: 15F & 15F-1, No. 508, Sec. 7, Zhongxiao E. Rd., Nangang Dist., Taipei City 115011, Taiwan (R.O.C.)
Phone: +886-2-27856892
Contact: Leticia Hong (leticiahong@aetherai.com)

3. Identification of the Subject Device:

Proprietary/Trade Name:	aetherSlide
Version:	101692
Classification Product Code:	QKQ
Regulation Number:	21 CFR 864.3700
Regulation Description:	Digital Pathology Image Viewing and Management Software
Review Panel:	88 - Pathology
Device Class:	II
510 (k) Submission Number:	K233126

4. Identification of the Predicate Device:

Predicate Device Name:	Philips IntelliSite Pathology Solution (PIPS)
Applicant:	Philips Medical Systems Nederland B.V
Classification Product Code:	PSY
Regulation number:	21 CFR 864.3700
Device Class:	II
Submission Number:	DEN160056

5. Indications for Use / Intended Use of the Device

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.

6. Description of the Device

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

Environment	Component	Minimum Requirements
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

7. Summary of Performance Testing

A series of tests were performed to assess the safety and effectiveness of aetherSlide. 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)"

Test	Result
Pixel-wise comparison	Pixel-wise comparison study was conducted to compare images reproduced by *aetherSlide* and PIPS IMS for the same iSyntax file to validate identical image reproduction. Test results showed that the 95th percentile of pixelwise differences between aetherSlide and PIPS IMS was less than 3 CIEDE2000, indicating that their output images

	are pixel-wise identical. Therefore, it was determined that color images reproduced by *aetherSlide* were visually adequate with respect to its intended use.
Turnaround time	The system requirements have been fulfilled: • When selecting a case, it should not take longer than 10 seconds until the image is fully loaded. • When panning the image (one quarter of the monitor) it shall not take longer than 7 seconds until the image is fully loaded. Turnaround times for opening an image and panning have been determined and found to be adequate for the intended use of the subject device.
Measurements	Measurement accuracy has been verified using a scanned image of the grid micrometer. *aetherSlide* has been found to perform accurate measurements with respect to its intended use.
Usability testing	The usability test was conducted per FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices (2016)". The test result demonstrated that the subject device has been found to be safe and effective for the intended users, uses, and use environments.

8. Substantial Equivalence Determination

The aetherSlide submitted in this 510(k) file is substantially equivalent in intended use, safety and performance claims to the cleared device, Philips IntelliSite Pathology Solution (PIPS) (DEN160056).

Table 3. Summary of Technological Characteristics

Item	Subject Device	Predicate Device	Substantial Equivalence Discussion
Manufacturer	aetherAI Co., Ltd.	Philips Medical Systems Nederland B.V.	
Trade Name	aetherSlide	Philips IntelliSite Pathology Solution (PIPS)	
Submission No.	K233126	DEN160056	
Indications for Use/Intended 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	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	***Similar*** When the subject device is used with PIPS UFS and Philips PS27QHDCR monitor, the software has similar indications for use to the Image Management System (IMS) application software of the predicate device. Thus, it would not affect the equivalence.

Item	Subject Device	Predicate Device	Substantial Equivalence Discussion
Manufacturer	aetherAI Co., Ltd.	Philips Medical Systems Nederland B.V.	
Trade Name	aetherSlide	Philips IntelliSite Pathology Solution (PIPS)	
Submission No.	K233126	DEN160056	
	intended for use with the Philips Ultra Fast Scanner (UFS) and the Philips PS27QHDCR monitor.	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	Surgical pathology slides prepared from FFPE tissue	***Similar*** The specimen type of the subject device is the digitized slides, which is obtained from the PIPIS UFS, and the predicate device includes the creation of digital images used PIPS UFS. Thus, the equivalence would not be affected.
Image File Format	iSyntax	iSyntax	***Same***
Image Manipulation	Panning, zooming, color manipulation function, annotations, and measurements	Panning, zooming, color manipulation function, annotations, and measurements	***Similar*** The performance of the

Item	Subject Device	Predicate Device	Substantial Equivalence Discussion
Manufacturer	aetherAI Co., Ltd.	Philips Medical Systems Nederland B.V.	
Trade Name	aetherSlide	Philips IntelliSite Pathology Solution (PIPS)	
Submission No.	K233126	DEN160056	
Functions	(only for distance)	(distance & area)	subject device is not affected and meet the requirements. Thus, it would not affect the equivalence.
Type of Software Application	Internet browser-based application	Internet browser-based application	***Same***
Device Components	aetherSlide imaging viewing software, aetherSlide Gateway	Ultra Fast Scanner (UFS), Image Management System (IMS), Display	***Similar*** The aetherSlide Gateway is used for uploading the slide into aetherSlide. This difference would not affect the performance of the subject device and its equivalence.
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	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	***Similar*** The performance of the subject device is not affected and meet the requirements.

Item	Subject Device	Predicate Device	Substantial Equivalence Discussion
Manufacturer	aetherAI Co., Ltd.	Philips Medical Systems Nederland B.V.	
Trade Name	aetherSlide	Philips IntelliSite Pathology Solution (PIPS)	
Submission No.	K233126	DEN160056	
	images from storage, performs further QC and reads WSI images of the slides to make a diagnosis.	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.	Thus, it would not affect the equivalence.
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.	***Similar*** The performance associated with image storage of subject device is not affected and meet the requirements. Thus, it would not affect the equivalence.

9. Similarity and Difference

The subject device has similar indications for use/intended use, similar technology/principle of operation, technological characteristics, and safety and performance to the predicate device, when used with the PIPS UFS scanner and the Philips PS27QHDCR monitor.

However, there is slight difference between the subject device and the predicate device which include the following aspect:

- Medical image communication software
  Once a slide image is acquired using PIPS UFS, according to its Instructions for Use, and becomes available in scanner database file systems, *aetherSlide* contains a Gateway which will automatically initiate uploading the slide image and corresponding metadata to the storage (not part of the device), or allow the operator to manually upload the slide image via aetherSlide Gateway. aetherSlide Gateway will perform integrity checks at the time of upload when data is copied to storage.

Nevertheless, verification activities were conducted on the subject device, and all tests were verified to meet the required acceptance criteria. The result of the verification tests indicated that aforementioned differences do not affect the indications for use/intended use of the subject device or raise any unresolved issues. Consequently, any differences between the subject device and the predicate device are insignificant and do not present any substantial equivalence concerns. The subject device is substantially equivalent to the predicate device as claimed.

10. Conclusion

After analyzing non-clinical safety and performance testing data, it can be concluded that when aetherSlide is used with the PIPS UFS scanner and the Philips PS27QHDCR monitor, it is substantially equivalent to the predicate device.