JelloX Biotech Inc.
Tzu-Han Fan
Medical Laboratory Scientist
No. 66-5, Shengyi 5th Rd., Zhubei City,
Hsinchu County, 302041
Taiwan

October 28, 2024

Re: K240303
Trade/Device Name: MetaLite DX Digital Pathology Software
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: QKQ
Dated: December 13, 2023
Received: February 2, 2024

Dear Tzu-Han Fan:

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)*
K240303

Device Name
MetaLite DX Digital Pathology Software

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

MetaLite DX Digital Pathology Software 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 for the purposes of pathology primary diagnosis. It is an aid to the pathologist to review, interpret and manage digital images of pathology slides.

MetaLite DX Digital Pathology Software 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. MetaLite DX Digital Pathology Software is intended for use with Philips Ultra Fast Scanner and the Barco MDPC-8127 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.

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510(k) SUMMARY

1. **Date of Summary:** October 28, 2024

2. **Submitter:**

Address:	No. 66-5, Shengyi 5th Rd., Zhubei City, Hsinchu County, 302041, Taiwan (R.O.C)
Phone:	+886-3-6583058 ext 204
Contact:	Tzu-Han Fan
Email	fancyhan@jellox.com

3. **Identification of the Device:**

Proprietary/Trade Name:	MetaLite DX Digital Pathology Software
Model Number:	MLDXUS
Version:	1.2.1
Regulation Description:	Whole Slide Imaging System
Review Panel:	88 – Pathology
Regulation Number:	21 CFR 864.3700
Product Code:	QKQ
Device Class:	Class II
510(k) Submission Number:	K240303

4. **Identification of the Predicate Device:**

Predicate Device Name:	Philips IntelliSite Pathology Solution (PIPS)
Model Number:	N/A
510(k) Number:	K203845
Manufacturer:	Philips Medical Systems Nederland B.V.
Regulation Number:	21 CFR 864.3700
Product Code:	PSY
Device Class:	Class II

5. Intended Use/ Indications for Use of the Device

For In Vitro Diagnostic Use

MetaLite DX Digital Pathology Software 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 for the purposes of pathology primary diagnosis. It is an aid to the pathologist to review, interpret and manage digital images of pathology slides.

MetaLite DX Digital Pathology Software 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. MetaLite DX Digital Pathology Software is intended for use with Philips Ultra Fast Scanner and the Barco MDPC-8127 display.

6. Device Description

MetaLite DX Digital Pathology Software, Model MLDXUS, version 1.2.1 is software designed for viewing digital pathology images of glass slides from the Philips IntelliSite Pathology Solution Ultra-Fast Scanner (PIPS-UFS), version 1.8.4 on Barco MDPC-8127 display.

MetaLite DX Digital Pathology Software is operated as follows:

Before scanning the slide on the PIPS-UFS, the technician performs quality control on the tissue of interest. The images captured by the PIPS-UFS are compressed using Philips' proprietary iSyntax format and are transmitted to the Philips Image Management System (IMS).

(1) After the Whole Slide Images (WSIs) are successfully, acquired by using PIPS-UFS, the WSIs are stored in the Local file system. A qualified pathologist will upload compatible iSyntax format digital pathology images, and the software will load them to the "Main Viewer" area of the graphical

interface for the pathologist to view.

(2) Once properly loaded, the pathologist will use the inherent features of the device (including tools that allow for adjusting the position and viewing angle of the image, measuring lengths between two coordinates, and adding annotations to specific regional areas).

(3) 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).

The software has various features such as zoom-in and zoom-out functions, scale display, thumbnail view, measurement function, annotation function, and panning function to help pathologists interpret, diagnose and manage digital whole slide images. The MetaLite DX Digital Pathology Software is validated for use with the components specified the tables below.

Table 1. Interoperable Components for Use with MetaLite DX Digital Pathology Software

Component	Manufacturer	Model
Scanner	Philips Medical Systems Nederland B.V.	Ultra Fast Scanner (UFS), Version 1.8.4
Display	Barco NV	MDPC-8127

Table 2. Computer Environment/System Requirements

Environment	Component	Minimum Requirements
Client PC		
Hardware	Processor	Intel® Core (TM) I7 11th Gen or above
	Memory	16GB or above
	Storage	USB Flash Drive 8GB or above
Software	Operating System	Windows 10 or above

7. Summary of Performance Testing

A series of tests were performed to assess the safety and effectiveness of the subject device, MetaLite DX Digital Pathology Software.

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)".

Test	Result
Pixel-wise comparison	Pixel-wise comparison study was conducted to compare images reproduced by MetaLite DX Digital Pathology Software and PIPS IMS for the same iSyntax file generated from UFS 1.8.4 to validate identical image reproduction. Test results showed that the 95th percentile of pixelwise differences between MetaLite DX Digital Pathology Software 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 MetaLite DX Digital Pathology Software were visually adequate with respect to its intended use.
Turnaround time	The turnaround time of opening, panning and zooming an image is within 5 seconds, which has 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 calibration scale slide. MetaLite DX Digital Pathology Software 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.

All test results demonstrate MetaLite DX Digital Pathology Software meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

8. Substantial Equivalence Determination

MetaLite DX Digital Pathology Software submitted in this 510(k) file is substantially equivalent in intended use, principles of operation, safety and performance to the cleared Philips IntelliSite Pathology Solution (PIPS) (K203845). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject device	Predicate device	Substantial equivalence determination
510(k) No.	K240303	K203845	N/A
Proprietary Name	MetaLite DX Digital Pathology Software	Philips IntelliSite Pathology Solution (PIPS)	
Manufacturer	JelloX Biotech Inc.	Philips Medical Systems Nederland B.V.	
Product Code	QKQ	PSY	
Classification	Class II	Class II	***Same***
Intended Use	For In Vitro Diagnostic Use MetaLite DX Digital Pathology Software 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 for the purposes of	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)	***Same*** Both software are designed to view and manage the digital image of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue.

Item	Subject device	Predicate device	Substantial equivalence determination
	pathology primary diagnosis. It is an aid to the pathologist to review, interpret and manage digital images of pathology slides. MetaLite DX Digital Pathology Software 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	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	

Item	Subject device	Predicate device	Substantial equivalence determination
	light microscopy review when making a diagnostic decision. MetaLite DX Digital Pathology Software is intended for use with Philips Ultra Fast Scanner and the Barco MDPC-8127 display.	obtained using PIPS.	
Specimen Type	Digitized surgical pathology slides prepared from FFPE tissue	Surgical pathology slides prepared from FFPE tissue	***Same***
Image file format	iSyntax	iSyntax	***Same***
Image Manipulation Functions	Panning, zooming, color manipulation function, annotations, and measurements (distance)	Panning, zooming, color manipulation function, annotations, and measurements (distance & area)	***Similar*** Same image manipulation function where subject device only measures distance
Type of Software Application	Stand-alone software	Internet browser-based application	***Different*** The difference in software application does not raise

Item	Subject device	Predicate device	Substantial equivalence determination
			new safety and effectiveness questions
Device Components	MetaLite DX Digital Pathology Software	Ultra Fast Scanner (UFS), Image Management System (IMS) and Display	***Different*** The subject device can substitute the IMS in the predicate device and this does not raise new safety and effectiveness questions
Principle of Operation	After WSI images are successfully acquired by using Philips IntelliSite Pathology Solution Ultra Fast Scanner (PIPS-UFS), the pathologist 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	***Same***

Item	Subject device	Predicate device	Substantial equivalence determination
		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 the local computer	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	***Different*** Network connectivity is not needed for subject software to function

Item	Subject device	Predicate device	Substantial equivalence determination
		WSI images of the slides to make a diagnosis	

9. Similarities and Differences

The subject device has similar indications for use/intended use and principle of operation as the predicate device.

There are three differences between the subject device and the predicate device, including the software application, the device component and the image storage.

For the device component, both devices are intended for viewing digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. The display used with subject product is Barco MDPC-8127, which has been confirmed to be substantially equivalent to the PS27QHDCR used in predicate device.

For the software application, the subject device is a stand-alone software, in contrast to the predicate device which operates as an internet browser-based software. The difference does not raise new safety and effectiveness questions.

Conversely, as the subject device does not require internet connectivity, it decreases the risk of vulnerability through the internet. The maintenance for the subject device includes installation and update is conducted by qualified specialist of JelloX Biotech Inc., this also enhances network security.

For the image storage, subject device would store images in local computer without using network to assess image data, compared to cloud storage, it significantly reduces the risk of data breaches.

The subject device has undergone safety and performance tests, and the results complied with the test requests. The subject device is substantially equivalent to the predicate device in intended use, principles of operation, safety and performance claims.

10. Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that when MetaLite DX Digital Pathology Software is used with the PIPS USF scanner and the Barco MDPC-8127 display, it is substantially equivalent to the predicate device.