



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K240303

B Applicant

JelloX Biotech Inc.

C Proprietary and Established Names

MetaLite DX Digital Pathology Software

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.

B Indication(s) for 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 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

MetaLite DX Digital Pathology Software, Model MLDXUS, version 1.2.0 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:

1. After the Whole Slide Images (WSIs) are successfully, acquired by using PIPS-UFS, the WSIs are stored in the Local file system. Scanned images are reviewed by scanning personnel such as histotechnicians to confirm image quality and initiate any re-scans before making it available to the pathologist per the instructions for use PIPS-UFS.
2. 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.
3. Once properly loaded, the pathologist performs quality control procedures per the Quality Control section below. The pathologist can use the device to view and review images using the device features such as zoom-in and zoom-out functions, scale display, thumbnail view, measurement function, annotation function, and panning function.
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).

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
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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

B Instrument Description Information:

1. Instrument Name:
MetaLite DX Digital Pathology Software
2. Specimen Identification:
The MetaLite DX Digital Pathology Software uses WSIs obtained from the PIPS-UFS of slides prepared from FFPE tissue. The reading pathologist selects a case (patient) from a local folder for viewing with the subject device.
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. Digital images (WSIs) are then obtained from these glass slides using the PIPS-UFS.
4. Calibration:
Not applicable.
5. Quality Control:
The subject device receives WSIs from local computer storage. All WSI files are quality-controlled images acquired from the scanner according to the scanner's instructions for use. The subject device specific quality control measures are performed by viewing the pathology images. Every pathologist should perform this test on review workstation before reading pathology images using the subject device to ensure that all scanned slide images have been imported and for every case, view the thumbnails in the pathology image window to verify that each slide that should be in the case is present.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Philips IntelliSite Pathology Solution

B Predicate 510(k) Number(s):
K203845

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K240303</u>	<u>K203845</u>
Device Trade Name	MetaLite DX Digital Pathology Software	Philips IntelliSite Pathology Solution (PIPS)
General Device Characteristic Similarities		
Intended Use/Indications For Use	<p>For In Vitro Diagnostic Use</p> <p>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.</p> <p>MetaLite DX Digital Pathology Software is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens.</p> <p>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.</p>	<p>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.</p> <p>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.</p>
Specimen Type	Digitized surgical pathology slides prepared from FFPE tissue.	Same
Diagnostic Image File Format	iSyntax	Same
Image Manipulation Functions	Panning, zooming, color manipulation function, annotations, and measurements (distance)	Panning, zooming, color manipulation function, annotations, and measurements (distance & area)

General Device Characteristic Differences		
Type of Software Application	Stand-alone software	Internet browser-based application
Device Components	MetaLite DX Digital Pathology Software	Ultra Fast Scanner (UFS), Image Management System (IMS) and Display
Principle of Operation	After WSI images are successfully acquired using the 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 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 WSI images of the slides to make a diagnosis.
End User's Interface	MetaLite DX Digital Pathology Software	PIPS Image Management System (IMS)

VI Standards/Guidance Documents Referenced:

1. FDA Guidance "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices". April 20, 2016.
2. FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices". February 3, 2016.
3. FDA Guidance "Content of Premarket Submissions for Device Software Functions". June 14, 2023.
4. FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". September 27, 2023.

5. AAMI TIR 45:2012 - Guidance on the use of AGILE practices in the development of medical device software.
6. IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, 13-79. Medical device software – Software life cycle processes.
7. IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, 5-129, Application of usability engineering to medical devices.
8. ISO 14971 Third Edition 2019-12, 5-125, Medical devices – Applications of risk management to medical devices.

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 the subject device, MetaLite DX Digital Pathology Software as specified below.

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 subject device was compared to 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) using the quantitative pixel-wise comparison method. The basis for the comparison was the CIEDE2000 color difference equation, ΔE . The devices were tested as operating with the intended components, including the scanner (PIPS UFS), image management system (PIPS IMS, MetaLite DX Digital Pathology Software) and display (Barco MDPC 8127).

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 version 1.8.4 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 2 magnification levels (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 MetaLite DX Digital Pathology Software. Each image set included 180 images that covered all combinations of 30 slides, 3 ROIs and 2 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 IMS image set was used as the reference to compare the MetaLite DX Digital Pathology Software image set to determine whether all the 180 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 (ΔE_{00}), is less than $3 \Delta E_{00}$. Testing results showed that the pixelwise differences across all 180 image-pairs were less than $3 \Delta E_{00}$. The mean 95th percentile ΔE_{00} value was 1.1 with the lowest value reported as 0 and the highest reported as 2.5. Testing results demonstrated that WSIs reproduced by MetaLite DX Digital Pathology Software are identical to images reproduced by the predicate device.

2. Turnaround Time

The turnaround times of the subject device were measured for the operations of image opening, panning, and zooming. Video recording software and calibration time software were used in the test to determine the turnaround time. The panning operation was executed by moving the image by one quarter of the screen using mouse dragging. The zooming operation was executed using the mouse wheel. Each operation was measured 10 times. The acceptance criterion was set at 7 seconds with respect to the device's intended use. Test results show that all opening, panning, and zooming operations were completed within 5 seconds.

3. Measurement

The measurement accuracy of the subject device was tested. A calibration scale slide with length marks of 100, 300, 600, 800, and 1000 μm was used as the target with known ground truth. The scale was measured in both horizontal and vertical orientations using the subject device. The error was calculated as the ratio of the difference between the measured length and the actual length to the actual length. The acceptance criterion was set at 5% with respect to the device's intended use. The test was conducted under magnification levels of 40X, 20X, 10X, and 1X. Test results show that the errors of all test cases were less than 2.4%.

4. Human Factor (Usability) Testing

The 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 MetaLite DX Digital Pathology Software device has been found to be safe and effective for intended users, users and use environments.

VIII Proposed Labeling:

The labeling supports 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.