



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K242244

B Applicant

Lumea, Inc.

C Proprietary and Established Names

Viewer+

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

Viewer+ 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. Viewer+ 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. Viewer+ is intended for use with Hamamatsu NanoZoomer S360MD Slide scanner and BARCO MDPC-8127 display.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

Viewer+, version 1.0.1, is a web-based software device that facilitates the viewing and navigating of digitized pathology images of slides prepared from FFPE-tissue specimens acquired from Hamamatsu NanoZoomer S360MD Slide scanner and viewed on BARCO MDPC-8127 display. Viewer+ renders these digitized pathology images for review, management, and navigation for pathology primary diagnosis.

Viewer+ is operated as follows:

1. Image acquisition is performed using the NanoZoomer S360MD Slide scanner according to its Instructions for Use. The operator performs quality control of the digital slides per the instructions of the NanoZoomer and lab specifications to determine if re-scans are necessary.
2. Once image acquisition is complete and the image becomes available in the scanner's database file system, a separate medical image communications software (not part of the device) automatically uploads the image and its corresponding metadata to persistent cloud storage. Image and data integrity checks are performed during the upload to ensure data accuracy.
3. The subject device enables the reading pathologist to open a patient case, view the images, and perform actions such as zooming, panning, measuring distances and areas, and annotating images as needed. After reviewing all images for a case, the pathologist will render a diagnosis.

Viewer+ operates with and is validated for use with the components specified the tables below:

Table 1. Interoperable Components for Use with Viewer+

Components	Manufacturer	Model
Scanner	Hamamatsu Photonics K.K.	NanoZoomer S360MD Slide scanner
Display	BARCO	MDPC-8127

Table 2. Computer Environment/System Requirements

Environment	Component	Minimum Requirements
Client PC		
Hardware	Processor	<ul style="list-style-type: none"> 1 CPU 4 cores 2.0GHz Standard consumer GPU, such as Intel, AMD, or NVIDIA with 2GB VRAM
	Memory	8 GB or more
	Network	100 Mbps or faster (1 Gbps recommended)
Software	Operating System/Browser	<ul style="list-style-type: none"> Windows (10 or higher) for <ul style="list-style-type: none"> Google Chrome (130.06723.117 or higher) Microsoft Edge (132.0.2.2849.80 or higher) Mozilla Firefox (132.0.1 or higher) Apple OS (13.7.2 Ventura or higher) for <ul style="list-style-type: none"> Apple Safari (18.1 (20619.2.8.11.10) or higher)

B Instrument Description Information:

1. Instrument Name:
Viewer+
2. Specimen Identification:
Viewer+ uses digital pathology images obtained from the Hamamatsu NanoZoomer S360MD Slide scanner of Hematoxylin and Eosin (H&E) stained glass slides. The reading pathologist selects a case (patient) from a worklist (within the device or external to the device) whereby the subject device fetches the associated images from the external image storage. The scanned images are identified based on the previously assigned specimen identifier such as the laboratory specimen accession number.
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 Hematoxylin and Eosin (H&E) stained. Digital images are then obtained from these glass slides using the Hamamatsu NanoZoomer S360MD Slide scanner.
4. Calibration:

Not applicable

5. Quality Control:

The scanning technician should perform quality control of all glass slides following the instructions. Upon scanning, quality control should be performed on all digital slide images following procedures defined by the scanner manufacturer prior to import into Viewer+. The pathologist should review all images to ensure that all expected slides have been imported by viewing the thumbnails and labels, and manually verifying the tissue specimen, block, and staining information is present.

V Substantial Equivalence Information:

A Predicate Device Name(s):

NanoZoomer S360MD Slide scanner system

B Predicate 510(k) Number(s):

K233027

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K242244</u>	<u>K233027</u>
Device Trade Name	Viewer+	NanoZoomer S360MD Slide scanner system
General Device Characteristic Similarities		
Intended Use/ Indications For Use	<p>For In Vitro Diagnostic Use</p> <p>Viewer+ 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. Viewer+ is not intended for use with frozen sections, 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. Viewer+ is intended for use with</p>	<p>The NanoZoomer S360MD Slide scanner system (“NanoZoomer System”) is an automated digital slide creation, viewing, and management system. The NanoZoomer System 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 NanoZoomer System is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens.</p> <p>The NanoZoomer System comprises the NanoZoomer S360MD Slide scanner, the NZViewMD Software and a compatible display that has been 510(k) cleared for use with the NanoZoomer system or a 510(k)-cleared display that has been assessed in accordance with the Predetermined Change Control Plan</p>

	Hamamatsu NanoZoomer S360MD Slide scanner and BARCO MDPC-8127 display.	(PCCP) for qualifying additional compatible displays. The NanoZoomer System 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 NanoZoomer System.
Specimen Type	Surgical pathology slides prepared from FFPE tissue	Same
Diagnostic Image File Format	Hamamatsu NDPI File	Same
Image Storage	User-supplied network attached storage	Same
General Device Characteristic Differences		
Image Manipulation and Review Functions	Functions for continuous panning and zooming, annotations, image adjustments, distance/area measurements, organize workload and view patient data, export images, and display of diagnostic status of images.	Functions for continuous panning and zooming, annotations, distance/area measurements, track visited areas, export images, discrete Z-axis displacement, and display of diagnostic status of images.
Type of Software Application	Internet browser-based application	PC-based installed application
End User's Interface	Viewer+	NZViewMD

VI Standards/Guidance Documents Referenced:

1. Guidance for Industry "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices", April 20, 2016.
2. Guidance for Industry "Applying Human Factors and Usability Engineering to Medical Devices", February 3, 2016.
3. IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, 13-79. Medical device software – Software life cycle processes.
4. ISO 14971 Third Edition 2019-12, 5-125, Medical devices – Applications of risk management to medical devices.
5. IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, 5-129, Application of usability engineering to medical devices.

6. AAMI TIR 45:2012, 13-36, Guidance on the use of AGILE practices in the development of medical device software.

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, Viewer+ 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 the comparators as listed in Table 3 below. 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_{00} . The devices were tested as operating with the intended components, including the scanner, specific file format, image management systems (subject device with the intended browsers, comparator [predicate device IRMS]) and display, as specified in the Table 3 below.

For each of the 4 configurations in Table 3 below, 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 Hamamatsu NanoZoomer S360MD Slide scanner to obtain 30 WSIs. For each of the 30 WSIs, 3 ROIs were selected by qualified personnel to represent various features in the tissue samples. Each ROI was captured at 3 magnification levels (10x, 20x, 40x).

The screenshots were captured from the intended display while viewing with the subject device and predicate device IRMS. 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.

For each configuration, two sets of images were collected: comparator (predicate device IRMS) and the subject device (Viewer+ with the intended browser). Each image set included 270 images that covered all combinations of 30 slides, 3 ROIs, and 3 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 comparator (predicate device IRMS) image set was used as the reference to compare the subject device image set to determine whether all the 270 image-pairs were identical for each configuration. 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 ΔE_{00} . Testing results showed that the pixelwise differences across all 270 image-pairs per configuration were less than 3 ΔE_{00} . The maximum (max), minimum (min), and mean of the 95th percentile ΔE_{00} value were reported in Table 3. Testing results demonstrated that WSIs reproduced by Viewer+ are identical to images reproduced by the predicate device.

Table 3. Viewer+ Pixelwise Comparison Testing Results

Scanner	Image File Format	Subject Device /Browser	Comparator (Predicate device IRMS)	Display	Results
Hamamatsu NanoZoomer S360MD Slide Scanner	NDPI	Viewer+ /Chrome	NZViewMD	BARCO MDPC-8127 display	max (95 th percentile ΔE_{00}) = 1.133 min (95 th percentile ΔE_{00}) = 0.550 mean (95 th percentile ΔE_{00}) = 0.773
		Viewer+ /Edge	NZViewMD		max (95 th percentile ΔE_{00}) = 1.133 min (95 th percentile ΔE_{00}) = 0.550 mean (95 th percentile ΔE_{00}) = 0.773
		Viewer+ /Firefox	NZViewMD		max (95 th percentile ΔE_{00}) = 1.141 min (95 th percentile ΔE_{00}) = 0.526 mean (95 th percentile ΔE_{00}) = 0.775
		Viewer+ /Safari	NZViewMD		max (95 th percentile ΔE_{00}) = 1.077 min (95 th percentile ΔE_{00}) = 0.620 mean (95 th percentile ΔE_{00}) = 0.791

2. Turnaround Time

The turnaround time for image loading, panning and zooming were tested in the subject device when using the 4 supported browsers (Google Chrome, Microsoft Edge, Mozilla Firefox, and Apple Safari) over different magnifications levels and over multiple fields of view (FOVs). Test results for different scenarios met the test acceptance criteria and showed acceptable turnaround time for the intended use of the subject device, as shown in table 4 below.

Table 4. Viewer+ Turnaround Time Study Test Results

Description	Test Method/Sample Size	Acceptance Criteria	Results (Seconds)
Loading	4 participants/4 browsers * 2 patient cases * 3 H&E-stained whole slide images per case = total of 24 image loading time measurements	Max 10 seconds per action	Mean = 3.3 Min = 2.0 Max = 8.0
Panning	4 participants/4 browsers * 2 patient cases * 3 H&E-stained whole slide images per case * 3 pans per image = total of 72 panning time measurements	Max 5 seconds per action	Mean = 1.3 Min = 1.0 Max = 3.0
Zooming	4 participants/4 browsers * 2 patient cases * 3 H&E-stained whole slide images per case * 3 zooms per image = total of 72 zooming time measurements	Max 5 seconds per action	Mean = 1.3 Min = 1.0 Max = 3.0

3. Measurement – distance and area

Measurement accuracy testing was performed to demonstrate that Viewer+ represents length and areal measurements accurately across multiple magnification levels. Four biological glass slides were scanned on Hamamatsu NanoZoomer S360MD Slide scanner, and then measured by qualified medical professionals using the Hamamatsu NZViewMD software and Viewer+ measurement tools on the supported Barco MDPC-8127 display. A randomized set of tests is chosen to test 4 biological glass slide images, 4 supported browsers (Google Chrome, Microsoft Edge, Mozilla Firefox, and Apple Safari), 4 rotations, 4 zooms, 2 directions, and 2 types of measurements (length and areal). The intended and reported metrics were recorded for each annotation. The differences between intended and reported measurements were calculated, as summarized below in Table 5. Acceptance criteria was set at +/- 0.1mm of pathologist annotation for length, and +/- 0.1mm² for area measurements. Test results showed that the acceptance criteria were met, and the subject device performed accurate measurements of length across multiple magnification settings with respect to its intended use.

Table 5. Viewer+ Measurement Results

Description	Acceptance Criteria	Results
Length	+/- 0.1mm of pathologist annotation	-0.02 mm < Variance < 0.0000 mm
Area	+/- 0.1mm ² of pathologist annotation	-0.0180 mm ² < Variance < 0.0600 mm ²

4. Human Factors (Usability) Testing

Usability testing was conducted per FDA's Guidance on Applying Human Factors and Usability Engineering to Medical Devices (2016). A summative human factors test, designed around critical user tasks and use scenarios using multiple representative users (pathologists), was conducted. 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 study. The Viewer+ 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.