Lumea, Inc.
Emre Gulturk
Regulatory Consultant
2889 Ashton Blvd #300
Lehi, UT 84043

March, 14, 2025

Re: K242244
Trade/Device Name: Viewer+
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: QKQ
Dated: July 19, 2024
Received: July 31, 2024

Dear Emre Gulturk:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242244

Device Name
Viewer+

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1. **Date of Summary:** March 11, 2025

2. **Submitter:** Lumea, Inc.

Address: 2889 Ashton Blvd #300
Lehi, UT 84043 USA

Phone: +1-612-396-1376

Contact: Emre Gulturk

Email: emre@lumeadigital.com

3. **Identification of the Device:**

Proprietary/Trade Name:	Viewer+
Version:	1.0.1
Regulation Description:	Whole Slide Imaging System
Review Panel:	88 - Pathology
Product Code:	QKQ
Device Class:	Class II
510(k) Submission Number:	K242244

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

Predicate Device Name:	NanoZoomer S360md Slide Scanner System
510(k) Number:	K233027
Manufacturer:	Hamamatsu Photonics K.K.
Regulation Number:	21 CFR 864.3700
Product Code:	PSY
Device Class:	Class II

5. **Intended Use/Indications 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.

6. 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.

The interoperable components of Viewer+ and other systems are provided below:

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	• 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	• Windows (10 or higher) for
		  ○ 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
		  ○ Apple Safari (18.1 (20619.2.8.11.10) or higher)

7. Summary of Performance Testing

A series of tests were performed to assess the safety and effectiveness of the subject device, Viewer+.

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 Viewer+ and NZViewMD for the same file generated from NanoZoomer S360md Slide Scanner to validate identical image reproduction. Test results showed that the 95th percentile of pixelwise differences between Viewer+ and NZViewMD was less than 3 CIEDE2000, indicating that their output images are pixel-wise identical. Therefore, it was determined that color images reproduced by Viewer+ were visually adequate with respect to its intended use.
Turnaround time	The turnaround time of opening, panning and zooming an image has been determined and found to be adequate for the intended use of the subject device.
Measurements	Measurement accuracy has been verified using scanned images of the biological slides. Viewer+ 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 Viewer+ meets the requirements of its pre-defined acceptance criteria and intended use and is substantially equivalent to the predicate device.

8. Substantial Equivalence Determination

Viewer+ submitted in this 510(k) file is substantially equivalent in intended use, principles of operation, safety and performance to the cleared NanoZoomer S360md slide scanner system (K233027). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Device & Predicate Device(s):	K242244	K233027	Substantial Equivalence Determination
Device Trade Name	Viewer+	NanoZoomer S360MD Slide scanner system	N/A
General Device Characteristic Similarities			
Intended Use/Indications 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	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. 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 (PCCP) for qualifying additional	***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.

Device & Predicate Device(s):	K242244	K233027	Substantial Equivalence Determination
	NanoZoomer S360MD Slide scanner and BARCO MDPC-8127 display.	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	Surgical pathology slides prepared from FFPE tissue	***Same***
Diagnostic Image File Format	Hamamatsu NDPI File	Hamamatsu NDPI File	***Same***
Image Storage	Same	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.	***Similar*** Same image manipulation function where subject device only measures distance/area
Type of Software Application	Internet browser-based application	PC-based installed application	***Different***

Device & Predicate Device(s):	K242244	K233027	Substantial Equivalence Determination
			The difference in software application does not raise new safety and effectiveness questions

9. Similarities and Differences

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

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

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

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 Viewer+ is used with the NanoZoomer S360md scanner and the Barco MDPC-8127 display, it is substantially equivalent to the predicate device.