January 8, 2026

Ge Healthcare
Tong Zhao
Sr. Lead Specialist, Regulatory Affairs, SW
500 W. Monroe St.
Chicago, IL 60661

Re: K253639
Trade/Device Name: View
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 18, 2025
Received: November 19, 2025

Dear Tong Zhao:

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); 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,

Jessica Lamb, PhD
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253639

Please provide the device trade name(s).

View

Please provide your Indications for Use below.

View is a software application that displays, processes, and analyzes medical image data and associated clinical reports to aid in diagnosis for healthcare professionals. It streamlines standard and advanced medical imaging analysis by providing a complete suite of measurement tools intended to generate relevant findings automatically collected for export and save purposes.

Typical users of this system are authorized healthcare professionals.

Mammography images may only be interpreted using a monitor compliant with requirements of local regulations and must meet other technical specifications reviewed and accepted by the local regulatory agencies. Lossy compressed mammographic images and digitized film screen images should not be reviewed for primary image interpretations with use of the View.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 18, 2025
Submitter:	GE Healthcare Establishment Registration Number - 3004526608 500 W. Monroe Street Chicago, IL 60661
Primary Contact Person:	Tong Zhao Sr. Lead Specialist, Regulatory Affairs, SW GE HealthCare (+86) 15142077290 Email: Tong.Zhao2@gehealthcare.com
Secondary Contact Person:	Elizabeth Mathew Director - Regulatory Affairs - AW & SEI GE HealthCare Tel: (262) 424-7774 Email: Elizabeth.Mathew@gehealthcare.com
Device Trade Name:	View
Common/Usual Name:	System, Image Processing, Radiological
Primary Classification Name: Primary Regulation Number: Primary Product Code: Classification:	Medical image management and processing system 21 CFR 892.2050 LLZ Class II
Primary Predicate Device Device name: Common/Usual Name: Manufacturer: 510(k) number:	 Universal Viewer UV GE Healthcare K211312

Classification Name:	Medical image management and processing system
Product Code:	LLZ
Classification:	Class II
Reference Device 1	
Device name:	VersaViewer
Common/Usual Name:	System, Image Processing, Radiological
Manufacturer:	GE Medical Systems SCS
510(k) number:	K243651
Primary Classification Name:	Medical image management and processing system
Primary Regulation Number:	21 CFR 892.2050
Primary Product Code:	LLZ
Secondary Product Code:	QIH
Classification:	Class II
Reference Device 2	
Device name:	Centricity PACS
Common/Usual Name:	PACS, Picture Archiving and Communication System
Manufacturer:	GE Healthcare
510(k) number:	K110875
Primary Classification Name:	Medical image management and processing system
Primary Regulation Number:	21 CFR 892.2050
Primary Product Code:	LLZ
Secondary Product Code:	GCJ
Classification:	Class II

Device Description:

View is a cloud-native software application designed to support healthcare professionals in the display, processing, and analysis of medical image data. It enhances diagnostic workflows by integrating intelligent tools, streamlined accessibility, and advanced visualization capabilities, including specialized support for breast imaging.

View brings together 2D imaging, basic 3D visualization and advance image analysis in a single, intuitive interface. This simplifies information access, improves workflow efficiency, and reduces the need for multiple applications.

Key features include:

- Smart Reading Protocol (SRP) which uses machine learning for creating and applying hanging protocols (HP)
- AI workflow to support both DICOM Secondary Capture Object & DICOM Structured Report for displaying AI findings and enabling rejection/modification of the AI findings.
- Displays 2D, 3D, and historical comparison exams in customizable layouts.
- Enables smooth transitions between 2D and 3D views, either manually or as part of hanging protocols.
- Advantage Workstation integration for deeper analysis through dedicated 3D applications.
- Offers a full suite of measurement, annotation and segmentation tools for DICOM images.
- Captures all measurements and annotations in a centralized findings panel.
- Enhanced access for DICOM images stored in the cloud server.
- Easy way to integrate with external systems using FHIRcast.
- Better user experience by having a native MIP/MPR/Smart Segmentation/Volume Rendering
- Seamless access to breast images through cloud with specific tools for Mammo images.

Intended Use

View is a software application that displays, processes, and analyzes medical image data and associated clinical reports to aid in diagnosis for healthcare professionals. It streamlines standard and advanced medical imaging analysis by providing a complete suite of measurement tools intended to generate relevant findings automatically collected for export and save purposes.

Indication for Use

View is a software application that displays, processes, and analyzes medical image data and associated clinical reports to aid in diagnosis for healthcare professionals. It streamlines standard and advanced medical imaging analysis by providing a complete suite of measurement tools intended to generate relevant findings automatically collected for export and save purposes.

Typical users of this system are authorized healthcare professionals.

Mammography images may only be interpreted using a monitor compliant with requirements of local regulations and must meet other technical specifications reviewed and accepted by the local regulatory agencies. Lossy compressed mammographic images and digitized film screen images should not be reviewed for primary image interpretations with use of the View.

Technology:

The proposed device View employs the same fundamental scientific technology as its predicate and reference devices.

Comparison:

The table below summarizes the key feature/technological differences and similarities between the predicate devices and subject device:

Specification	Predicate Device: Universal Viewer (K211312)	Subject Device: View	Discussion of Differences
Software deployment platform	Both On-premises and Cloud deployment	Cloud deployment	**Substantially Equivalent**
Native Breast Imaging	Yes	Yes	**Substantially Equivalent** Both the predicate and subject devices provide native access to breast imaging workflows and tools to support screening and diagnostic workflows and the display of multi-vendor images. They both support Mammography and Tomography display, ACR View, Stepped hanging protocols, Tomo Locator and CAD Structured Reporting display.
Smart Reading Protocols (SRP)	Yes (not available for Mammo and PET)	Yes (not available for Mammo)	**Substantially Equivalent** SRP machine learning algorithm is directly ported from the predicate device to the subject device. There are no changes in core functionality nor machine learning algorithm.
AI Workflow Support	Yes	Yes	**Substantially Equivalent** Both the predicate device and subject device display and delete AI findings present on DICOM Secondary Capture images. Subject device additionally allows users to display/reject/modify AI findings in DICOM Structured Report and save it as user DICOM SR.
Integration API	Yes	Yes	**Substantially Equivalent** In the predicate device Universal Viewer, Propriety API is used for integration with external systems. The subject device, View, uses

Specification	Predicate Device: Universal Viewer (K211312)	Subject Device: View	Discussion of Differences
			FHIRcast API for integration with external systems.
Image Rendering Types	Axial / Coronal / Sagittal Oblique / 3D / Volume Rendering / MIP / minIP	Axial / Coronal / Sagittal Oblique / 3D / Volume Rendering / MIP / minIP / Average Rendering	**Substantially Equivalent** Both the predicate and subject devices include the Axial / Coronal / Sagittal and Oblique / 3D / Volume Rendering / MIP / minIP. In addition, the subject device also supports Average Rendering. Average Rendering already exists in the reference device VersaViewer (K243651).
Set of segmentation tools	No	Yes Segmentation tools support creation and editing of findings on 2D and 3D views in axial, coronal or sagittal standard orientation. • Smart Brush automatically adapts brush shape to the image density / signal. • Threshold Brush selects values within a given threshold, with the possibility to add a factor to smooth contour edges.	**Substantially Equivalent** New Segmentation tools are implemented in the subject device. The same segmentation tools are already present in the reference device, VersaViewer (K243651).

Determination of Substantial Equivalence:

Summary of Testing

View has been designed and tested per GE HealthCare's quality system. It was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. Following GE HealthCare's risk management process, all hazards have been mitigated to as far as possible. The proposed device complies with NEMA PS 3.1-3.20 2024e Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard.

The following quality assurance measures were applied to the development of the device:

- Requirements Definition
- Risk Analysis
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
- Software Design Verification and Validation testing (including safety)

Software documentation level was determined to be Basic Documentation Level.
The Smart Reading Protocol function, which uses machine learning for creating and applying hanging protocols, was tested on various imaging modality datasets representative of the clinical scenarios where View is intended to be used. A comparison was performed between the predicate device (Universal Viewer) and the subject device (View) and showed that the devices are equivalent.

The proposed device View has been successfully verified and validated.

Conclusion:

View has substantial equivalent technological characteristics as its predicate device.

Based on development under GE HealthCare's quality system, successful design verification, software documentation for a "Basic Documentation Level", GE HealthCare concludes that the proposed device View is substantially equivalent to, and hence as safe and as effective for its Intended Use as the legally marketed predicate device.