April 21, 2025

GE Medical Systems SCS
℅ Peter Uhlir
Regulatory Affairs Program Manager
283, rue de la Miniere
BUC, 78530
FRANCE

Re: K243651
Trade/Device Name: VersaViewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, QIH
Dated: November 26, 2024
Received: March 21, 2025

Dear Peter Uhlir:

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,

for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems 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

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.

Submission Number *(if known)*

K243651

Device Name

VersaViewer

Indications for Use *(Describe)*

VersaViewer is a medical diagnosis software supporting 2D, 3D and 4D medical images series for their processing and analysis through customizable layouts allowing multimodality review. It streamlines standard and advanced medical imaging analysis by providing a suite of measurements capabilities. It is designed for use by trained healthcare professionals and is intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions. VersaViewer is not intended for the displaying of digital mammography images for diagnosis.

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) Number K243651

510(k) Summary

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

Date:	November 26, 2024
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283 rue de la Miniere 78530 Buc, France
Primary Contact Person:	Peter Uhlir Regulatory Affairs Program Manager GE HealthCare Tel: (+36) 70-436-9317 Email: peter.uhlir@gehealthcare.com
Secondary Contact Person:	Camille Vidal Senior Director Regulatory Affairs – Digital, AW & SEI GE HealthCare Tel: 240-280-5356 Email: Camille.Vidal@gehealthcare.com
Device Trade Name:	VersaViewer
Common/Usual Name:	System, Image Processing, Radiological
Primary Classification Name: Primary Regulation Number: Primary Product Code: Secondary Product Code: Classification:	Medical image management and processing system 21 CFR 892.2050 LLZ QIH Class II

Primary Predicate Device	
Device name:	Volume Viewer Plus
Common/Usual Name:	System, X-Ray, Tomography, Computed
Manufacturer:	GE Medical Systems SCS
510(k) number:	K041521
Classification Name:	Computed tomography X-Ray System
Regulation Number:	21 CFR 892.1750
Product Code:	JAK
Classification:	Class II
Reference Device	
Device name:	Spectral Bone Marrow
Common/Usual Name:	System, X-Ray, Tomography, Computed
Manufacturer:	GE Medical Systems, LLC
510(k) number:	K223514
Regulation Number / Classification Name / Product Code:	21 CFR 892.1750 / Computed tomography X-ray system / JAK 21 CFR 892.2050 / Automated Radiological Image Processing Software / QIH
Classification:	Class II

Device Description:

VersaViewer is a software application for processing and analysis of 2D, 3D and 4D medical imaging data. The application provides adaptive layout to display selected series and, common radiology toolset to perform measurements. It aims to enable the review of medical imaging acquisitions for which a dedicated advanced visualization application is not required.

VersaViewer has the following functionalities:

- Reconstruct and display 2D, 3D and 4D medical images from multiple modalities.
- Display relevant series in an adaptive layout based on user selection.
- Access and dynamically load series of interest through embedded Series Selector.
- Allow to select different image rendering modes such as Volume Rendering, MIP (maximum intensity projection) /MinIP (minimum intensity projection) /

- Average, MPR (multiplanar reformation) and Oblique.
- Basic image review tools including paging, WW/WL adjustment and zoom. 3D volumes can be visualized in adjustable multi-oblique planes.
- Set of annotation, measurement, and segmentation tools.
- Dedicated panel collects findings as they are deposited on the images and enables user to manage them.
- Images and findings export options.

VersaViewer also includes One View as an optional feature.

One View provides reformatted views to assist radiologists in interpreting various types of spectral exams by projecting GSI (Gemstone Spectral Imaging) material decomposition images over monochromatic and color overlay.

Intended Use:

VersaViewer is a medical diagnosis software designed to process 2D, 3D and 4D medical images series, providing radiologists and clinicians with a display framework and tools to ease multimodality imaging review and analysis.

Indication for Use:

VersaViewer is a medical diagnosis software supporting 2D, 3D and 4D medical images series for their processing and analysis through customizable layouts allowing multimodality review. It streamlines standard and advanced medical imaging analysis by providing a suite of measurements capabilities. It is designed for use by trained healthcare professionals and is intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

VersaViewer is not intended for the displaying of digital mammography images for diagnosis.

Technology:

The proposed device VersaViewer 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	Primary Predicate Device: Volume Viewer Plus (K041521)	Subject Device: VersaViewer	Comparison
Targeted anatomy and imaging modality	All anatomies CT, MR, PET, NM, XACT DICOM images	All anatomies CT, MR, PET, NM, XACT, SCPT, US, CR, DX, RF, XA, MR PJN, CT GSI, MG and breast tomosynthesis (for presentation only).	**Substantially equivalent.** The Image Support of proposed device is adapted and compatible with acquisition images evolution. The image support has been successfully verified and validated. No safety and effectiveness issues are raised by the expanded scope of modality coverage. VersaViewer is not intended for the displaying of digital mammography images for diagnosis.
Images Rendering Types	Axial / Coronal / Sagittal Oblique / 3D / Volume Rendering / MIP / minIP / Average Rendering / Surface Rendering	Axial / Coronal / Sagittal Oblique / 3D / Volume Rendering / MIP / minIP and Average Rendering	**Substantially Equivalent** Both the predicate and proposed devices include the Axial / Coronal / Sagittal and Oblique / 3D / Volume Rendering / MIP / minIP and Average Rendering types.
Images manipulation	The following image manipulations are available: • Magnification • Roam/pan • ww/wl and , ww/wl presets • simple oblique • link / unlink series.	Usual image manipulations are accessible directly from active annotations in viewports, through mouse actions or icons in the toolbar: • Zoom in / zoom out • Roam / pan • WW/WL manual adjustments and presets panel • Multi oblique tool: displays three adjustable obliques planes • Link / unlink series	**Substantially Equivalent** All the functionalities existed in Volume Viewer Plus except the multi-oblique tool. This tool is like simple oblique mode, available in Volume Viewer Plus. It has been added in the subject device, creating 3 orthogonal obliques views. This function facilitates user's review but doesn't add or remove any information.

Specification	Primary Predicate Device: Volume Viewer Plus (K041521)	Subject Device: VersaViewer	Comparison
Set of segmentation tools	Not available	Yes Segmentation tools allow to create or edit 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** Brush is a new segmentation-based measurement, but its result can be obtained by combination of existing functions already presented in the predicate device. It improves and optimizes the workflow. This function has already cleared in GEHC legacy device, BreView (K233714).
Export	DICOM Secondary Capture export	It provides a variety of methods for sharing the results with clinical partners. • Export images and findings can be saved as SCPT series and networked to DICOM destinations for structured reporting purposes. • Copy images and findings to paste into personalized communications.	**Substantially Equivalent** Both the predicate and subject device have capabilities to export the information displayed in the application.

Specification One View	Reference Device: Spectral Bone Marrow (K223514)	Subject Device: VersaViewer	Comparison
Clinical Workflow	Automated	Automated	**Substantially Equivalent** In the subject device, a fully automated workflow generates the desired images (colored MD images of the segmented bone region overlaid on the monochromatic base or Virtual Unenhanced images) as secondary capture DICOM objects and networks them to the preconfigured DICOM destinations (e.g. PACS) for the user to review. Similar workflow already exists in reference device, Spectral Bone Marrow (K223514). This change in the subject device greatly improves the overall efficiency of the review workflow.
Segmentation technology	Deep Learning based segmentation (bone)	Deep Learning based segmentation (lung, liver, bone, aorta, heart and body (entire body))	**Substantially equivalent** The One View feature includes CT Multi Organ segmentation that provides a fully automatic segmentation based on deep-learning model for six body parts as lung, liver, bone, aorta, heart and body (entire body), each with its own distinctive contrast parameters: The deep learning algorithm employed in the subject device have been successfully verified and validated, through comparison to legacy segmentation algorithms.

Specification One View	Reference Device: Spectral Bone Marrow (K223514)	Subject Device: VersaViewer	Comparison
Algorithm Output	Spectral contrast parameters (Base keV in greyscale, Material density image overlay of Water (HAP) in color), utilized visualize bone marrow.	Spectral contrast parameters (keV, MD overlay in greyscale or color), utilized to create organ contrast.	**Substantially Equivalent** One View option of VersaViewer adjusts the imaging parameters of several body parts automatically and displays them in one image. In the reference device, Spectral Bone Marrow (K223514) the fused image of colored material density (MD) images (e.g water (HAP)) of the segmented bone region overlaid onto the base monochromatic spectral CT images or Virtual Unenhanced images, as secondary capture DICOM series. In the subject device same algorithm output is use but it is applied for other six body parts as lung, liver, bone, aorta, heart and body (entire body),

Determination of Substantial Equivalence:

Summary of Non-Clinical, Design Control Testing

VersaViewer has successfully completed the design control testing per GE HealthCare's quality system. It was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The proposed device complies with NEMA PS 3.1 - 3.20 (2023) 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
- Performance testing (Verification, Validation)
- Safety Testing (Verification)

The proposed VersaViewer has been successfully verified on the AW Server (K081985) platform. All the testing and results did not raise new or different questions of safety and effectiveness other than those already associated with predicate devices. The documentation level was determined to be Basic Documentation Level.

In addition, Engineering has performed bench testing for the newly introduced deep learning algorithm in the subject device for automated segmentation of six body parts as lung, liver, bone, aorta, heart and body (entire body) using a database of retrospective CT exams. This database of exams is representative of the clinical scenarios where VersaViewer is intended to be used, with consideration of acquisition protocols and clinical indicators. The result of the algorithm validation showed that the algorithm successfully passed the defined acceptance criteria.

Conclusion:

VersaViewer has substantial equivalent technological characteristics as its predicate devices.

GE HealthCare's quality system's design, verification, and risk management processes did not identify any new questions of safety or effectiveness, hazards, unexpected results, or adverse effects stemming from the changes to the predicates.

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