GE Healthcare GmbH
℅ Brandon O'Shea
Sr. Regulatory Affairs Manager
GE HealthCare
9900 Innovation Drive
Wauwatosa, WI 53225

July 2, 2024

Re: K241300
Trade/Device Name: ViewPoint 6
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 8, 2024
Received: May 9, 2024

Dear Brandon O'Shea:

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.

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
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic 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)*

K241300

Device Name

ViewPoint 6

Indications for Use *(Describe)*

ViewPoint 6 is intended to be used in medical practices and in clinical departments and serves the purposes of diagnostic interpretation of images, electronic documentation of examinations in the form of text and images and generation of medical reports primarily for diagnostic ultrasound.

ViewPoint 6 provides the user the ability to include images, drawings, and charts into medical reports. ViewPoint 6 is designed to accept, transfer, display, calculate, store and process medical images and data, and enables the user to measure and annotate the images. The medical images, which ViewPoint 6 displays to the user, can be used for diagnostic purposes.

ViewPoint 6 is intended for professional use only. ViewPoint 6 is not intended to be used as an automated diagnosis system.

ViewPoint 6 is not intended to operate medical devices in surgery related procedures.

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.

510(k) Summary

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

807.92(a)(1) – Submitter Information	
Date	08 May 2024
Submitter	GE Healthcare GmbH Oskar-Schlemmer-Straße 11 80807 München, Germany
Primary Contact Person	Brandon O'Shea Sr. Regulatory Affairs Manager GE HealthCare, Ultrasound Email: brandon.oshea@gehealthcare.com Ph: (414) 323-3147
Secondary Contact Person	Gabriel Carniel Regulatory Affairs Specialist GE HealthCare, Ultrasound Email: gabriel.carniel@gehealthcare.com
807.92(a)(2) – Device Information	
Device Trade Name	ViewPoint 6
Common/Usual Name	System, Image Processing, Radiological
Regulation Name	Medical image management and processing system
Regulation Number	21 CFR 892.2050
Regulation Class	Class II
Product Code	LLZ
Review Panel	Radiology
807.92(a)(3) – Predicate Device	
510(k) Number	K203677
Manufacturer	GE Healthcare GmbH
Predicate Device(s)	ViewPoint 6
The predicate device has not been subject to a design-related recall	
807.92(a)(4) – Device Description	

Device Design

ViewPoint 6 is an image archiving and reporting software for medical practices and clinical radiological departments. It is used for diagnostic interpretation of images and other data. ViewPoint 6 is for professional use only and enables quick diagnostic reporting with standardized terminology. It is designed with intuitive graphical user interfaces (GUIs) and is based on Microsoft Windows® with defined hardware requirements.

Viewpoint 6 provides exam type specific reporting forms for various medical care areas. Forms are composed of different sections with data entry fields. The documentation can include measurements, exam findings, images and graphs. All data is saved in the ViewPoint 6 database and can be compiled to a professional report. Images and image sequences can be reviewed in the ViewPoint 6 display area based on user preference.

ViewPoint 6 supports both a single workstation and a client/browser – server setup. The number of user licenses determines how many workstations in the network have concurrent access to the database. Access can be limited to read-only functionality.

Environment of Use
ViewPoint 6 is intended to be utilized across ultrasound care areas and environments.

Principle of Operation and Deployment
ViewPoint 6 software is a server-based application with client-server architecture, accessed via client computers or mobile devices as well as browser-based systems. Viewpoint 6 is installed on client provided servers within a hospital network.

The software comes with features to view, annotate, measure, calculate, save and retrieve clinical data (including images via DICOM format) to support patient documentation and record keeping related to ultrasound image scans. Additionally, the software is available for patient administrative tasks such as appointment scheduling and exam billing.

This product does not control or alter any of the medical devices providing data across the hospital network.

807.92(a)(5) – Indications for Use

ViewPoint 6 is intended to be used in medical practices and in clinical departments and serves the purposes of diagnostic interpretation of images, electronic documentation of examinations in the form of text and images and generation of medical reports primarily for diagnostic ultrasound.

ViewPoint 6 provides the user the ability to include images, drawings, and charts into medical reports. ViewPoint 6 is designed to accept, transfer, display, calculate, store and process medical images and data, and enables the user to measure and annotate the images. The medical images, which ViewPoint 6 displays to the user, can be used for diagnostic purposes.

ViewPoint 6 is intended for professional use only. ViewPoint 6 is not intended to be used as an automated diagnosis system.

ViewPoint 6 is not intended to operate medical devices in surgery related procedures.

807.92(a)(6) – Comparison of Intended Use and Technological Characteristics

The table below compares the intended use and technological characteristics of the subject and predicate device.

Specification	**Predicate Device ViewPoint 6 (v6.12) K203677**	**Subject Device ViewPoint 6 (v6.15) K241300**
Patient Population	All patient types	All patient types
Environment of Use	ViewPoint 6 is intended to be used in medical practices and in clinical departments	ViewPoint 6 is intended to be used in medical practices and in clinical departments **as well as remote support locations with MobileConnect**

Design	• System is based on Windows operating system • Central SQL database • Native Client to Server System • Client communicates to server via CORBA, SQL and files • One Software version with configurable languages	• System is based on Windows operating system • Central SQL database • Native Client **and Browser Client(s)** to Server System • Client communicates to server via **REST API**, SQL and files • One Software version with configurable languages
Performance	Performance dependent on customer hardware but minimum hardware requirements for acceptable performance are defined in the System Requirements	Performance dependent on customer hardware but minimum hardware requirements for acceptable performance are defined in the System Requirements
Compatibility with other devices / Accessories	Compatibility with other devices: • EchoPAC Plug-in (K200852) • 4D View (K182750)	Compatibility with other devices: • EchoPAC Plug-in (**K220940**) • 4D View (K182750)
Interfaces	Public (bidirectional interfaces) • DICOM Interface to the imaging modality (scanners) • DICOM Interface to PACS • HL7 Interface • HL7 exam data import interface to a laboratory system or Trium CTG Online • BDT/GDT Interface • HTTPS+SOAP (only available in Sweden) Private (service/non-public interfaces) • TCP+TLS (SQL) • TCP (DICOM Fast Routing)	Public (bidirectional interfaces) • DICOM + **DICOM (TLS)** Interface to the imaging modality (scanners) • DICOM Interface to PACS • HL7 Interface • HL7 exam data import interface to a laboratory system or Trium CTG Online • BDT/GDT Interface • HTTPS+SOAP (only available in Sweden) Private (service/non-public interfaces) • TCP+TLS (SQL) • TCP (DICOM Fast Routing) • **FHIR Interface (service/non-public)** • **HTTPS (REST, WAMP, WS, WebDAV)**
Data Sources / Connectivity / Outputs	Data Sources (inputs) • Imaging Modalities (scanners) • Electronic Health Record (EHR/HIS) • Picture Archiving and Communication System (PACS) • General HL7 connected health systems Connectivity & Output • Fax Device • Network Attached Storage • Imaging Modalities (Scanners) • Electronic Health Record (EHR/HIS) • Picture Archiving and Communication System (PACS)	Data Sources (inputs) • Imaging Modalities (scanners) • Electronic Health Record (EHR/HIS) • Picture Archiving and Communication System (PACS) • General HL7 connected health systems Connectivity & Output • Fax Device • Network Attached Storage • Imaging Modalities (Scanners) • Electronic Health Record (EHR/HIS) • Picture Archiving and Communication System (PACS)
Image Management	• Ability to capture and view images • Ability to handle DICOM and other image formats (JPG and TIF) but convert all images to DICOM for archiving • Manage single images as well as image sequences and volume data • Arrange images in an exam • Select images to include in a report • Take measurements on images • Add annotations to images • Adjust image parameters • Compare images • Post-processing images using 4D View or	• Ability to capture and view images • Ability to handle DICOM and other image formats (JPG and TIF) but convert all images to DICOM for archiving • Manage single images as well as image sequences and volume data • Arrange images in an exam • Select images to include in a report • Take measurements on images • Add annotations to images • Adjust image parameters • Compare images • Post-processing images using 4D View or

	EchoPAC	EchoPAC
Examination Management	Reporting Module Areas • Obstetrics • Maternity Documentation • Gynecology • Breast Ultrasound • Abdomen and Small Parts • Endoscopy • Vascular • Echocardiography • General Report	Reporting Module Areas • Obstetrics • Maternity Documentation • Gynecology • Breast Ultrasound • Abdomen and Small Parts • Endoscopy • Vascular • Echocardiography • General Report • **Point of Care Ultrasound (POCUS)**
Report Editing and Management	• Ability to generate reports which include exam results, images and graphs • Ability to create exam templates for exam types and care areas or specific departments • Ability to set default templates for specific exam types • Capability to print or fax reports to specific contact lists • Ability to auto-fill a report with selected information from a prior study or other values within a report • Dark mode reports for light-reduced environments	• Ability to generate reports which include exam results, images and graphs • Ability to create exam templates for exam types and care areas or specific departments • Ability to set default templates for specific exam types • Capability to print or fax reports to specific contact lists • Ability to auto-fill a report with selected information from a prior study or other values within a report • Dark mode reports for light-reduced environments

Calculation & Analysis (within Examination Management)	• Gestational age
	• Physical patient status calculations (BMI, PI/RI for Doppler values, etc.)
	• Gynecology reporting
	  ○ Ovarian tumor classification according to IOTA LR2 Model
	  ○ Ovarian tumor classification according to IOTA Simple Rules Model
	  ○ IOTA ADNEX Model (Ovarian Tumor Analysis Model of IOTA medical group)
	  ○ Carotid arteries ultrasound exam (extracranial): Automated calculation based on Peak systolic and End-diastolic velocities index
	• Echocardiography and Vascular ultrasound reporting:
	  ○ Standard calculations like Echocardiography and Doppler automated calculation
	  ○ Echocardiography Reporting
	  ▪ Support of Z-Scores
	• Head and Neck Reporting
	  ○ Automated calculations
	  ○ ACR TI-RADS Thyroid Risk-Stratification System
	• Obstetrics reporting
		• Gestational age
		• Physical patient status calculations (BMI, PI/RI for Doppler values, **expanded automated calculation for Surface Area by Haycock BSA formula,** etc.)
		• Gynecology reporting
		  ○ Ovarian tumor classification according to IOTA LR2 Model
		  ○ Ovarian tumor classification according to IOTA Simple Rules Model
		  ○ IOTA ADNEX Model (Ovarian Tumor Analysis Model of IOTA medical group)
		  ○ Carotid arteries ultrasound exam (extracranial): Automated calculation based on Peak systolic and End-diastolic velocities index (**including Sr. Mary Ratio; ICA prox PSV/CCA distal EDV ratio**)
		• Echocardiography and Vascular ultrasound reporting:
		  ○ Standard calculations like Echocardiography and Doppler automated calculation
		  ○ Echocardiography Reporting
		  ▪ Support of Z-Scores (**including publications from Pediatric Heart Network**)
		  ▪ **Automated simple Echocardiography measurement calculations such as indexed values (over BSA)**
		  ▪ **Automated report generation for echocardiography reporting based on normalized value references**

		• Head and Neck Reporting
		  ○ Automated calculations
		  ○ ACR Ti-RADS Thyroid Risk-Stratification System
		  ○ **Thyroid nodules overview table (trending table for thyroid lesion sizes, location and TI-RADS grading**)
		• Obstetrics reporting (**with extended fetal biometry charts and graphs**)

Data Privacy and Security	• Centralized user management through link to Microsoft Active Directory by LDAP • Database Encryption • SmartCard authentication • Clear short time store (STS) per station on user logoff • LDAP Support • FileShare • CORBA	• Centralized user management through link to Microsoft Active Directory by LDAP • Database Encryption • SmartCard authentication • Clear short time store (STS) per station on user logoff • LDAP Support • **REST API** • **DICOM (TLS) support enabled**
Other Functions (non-device functions)	• Administrate Appointments (ability to schedule appointments) • Coding and billing • Order Management • Contact Management • User Management • Analytics	• Administrate Appointments (ability to schedule appointments) • Coding and Billing • Order Management • Contact Management • User Management • Analytics • **Automatic Assignment of Studies to an Exam**

User Interfaces	• ViewPoint 6 Native Client (PC)	• ViewPoint 6 Native Client (PC)
		• **ViewPoint 6 Browser Client(s)**
		  ○ **WebConnect Client (PC/Tablet)**
		  ○ **MobileConnect Client (Tablet/Phone)**

Supported Operating System(s)	Operating System(s) Native Client: • Windows 8.1, Windows 10, Windows Server 2012, Windows Server 2016, Windows Server 2019	Operating System(s) Native Client: • Windows 10, Windows 11, Windows Server 2016, Windows Server 2019, **Windows Server 2022** **Operating System(s) Browser Client (WebConnect):** • **Mozilla Firefox (minimum version 103.2)** • **Microsoft Edge Extended Stable Channel: Version 105.0.1343.42** • **Google Chrome Version 105.0.5195.127** **Operating System(s) Browser Client (MobileConnect):** • **iOS – Apple Safari: Version 16.3 and above** • **Android – Google Chrome Version 111 and above**

The proposed ViewPoint 6 application is substantially equivalent to the ViewPoint 6 (K203677) application with regards to intended use, capabilities, technological characteristics, security characteristics, safety and effectiveness.

The proposed ViewPoint 6 application employs the same fundamental scientific technology as its predicate device.

807.92(b)(1) – Performance Testing	
Summary of Non-Clinical Tests	Software was evaluated as recommended in the 2023 FDA guidance document "Content of Premarket Submissions for Device Software Functions." The ViewPoint 6 application was developed following the GE HealthCare Quality Management System. The following activities were successfully completed: ▪ Risk Analysis / Management ▪ Requirements Reviews ▪ Design Reviews ▪ Testing on unit level (Module Verification) ▪ Integration testing (System Verification) ▪ Performance testing (Verification & Validation) ▪ Safety testing (Verification) The ViewPoint 6 application has also been subject to the following voluntary standards / non-clinical V&V activities: ▪ IEC 62366-1:2016-10, Medical devices – Part1: Application of usability engineering to medical devices ▪ IEC 62304:2015-06, Medical device software – Software life cycle processes ▪ NEMA PS 3.1-3.20 (2023e), Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) ▪ ISO 14971:2019-12, Medical devices – Application of risk management to medical devices ▪ IEC 82304-1:2016-10, Health software – Part 1: General requirement for product safety ▪ ISO 15223-1:2021-07, Medical devices – Symbols to be used with information to be supplied by the manufacturer ▪ ISO 20417:2021-04, Medical devices – Information to be supplied by the manufacturer Successful completion of design verification and validation testing was performed to confirm that software and user requirements have been met. Cybersecurity was evaluated as recommended in the 2023 FDA guidance document "Cybersecurity in Medical Devices: Quality Systems Considerations and Content of Premarket Submissions." Interoperability was evaluated as recommended in the 2017 FDA guidance document "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices."

	No additional testing was required beyond the testing per the standards and the verification testing from the **Software/Firmware Section** to support substantial equivalence.
807.92(b)(2) – Summary of Clinical Tests	
Summary of Clinical Tests	The similarities and differences between the subject device and the predicate device, were determined not to have a significant impact on the device's performance, the clinical performance, and the actual use scenarios. Therefore, the subject of this premarket submission, ViewPoint 6, did not require clinical studies to support substantial equivalence.
807.92(b)(3) - Conclusion	
The performance data described above demonstrate that the proposed ViewPoint 6 application is as safe and effective as the predicate device and supports a determination of substantial equivalence.	