GE Medical Systems Ultrasound and
Primary Care Diagnostics, LLC
℅ Tracey Ortiz
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA WI 53226

January 6, 2020

Re: K192917
Trade/Device Name: ViewPoint 6
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 14, 2019
Received: November 15, 2019

Dear Tracey Ortiz:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)* **K192917**

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.

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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510(k) Summary

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

Date:	October 11, 2019
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Tracey Ortiz Regulatory Affairs Director GE Healthcare T:(262)676-6120
Secondary Contact Person:	Wei Liwen Regulatory Affairs Leader GE Healthcare
Trade Name:	ViewPoint 6
Common/Usual Name:	PACS-Picture archiving and communications system
Classification Names:	Class II
Product Code:	LLZ, Picture archiving and communications system, 21 CFR 892.2050, 90-LLZ
Primary Predicate Device:	ViewPoint 6 (K173456)
Product Code:	LLZ, Picture archiving and communications system, 21 CFR 892.2050, 90-LLZ
Reference Device(s):	Voluson E10 (K192159) Versana Balance (K191792)
Product Code:	IYN (primary) & IYO (secondary) IYN, Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550, 90-IYN IYO, Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO

Device Description:	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. It provides different calculations and tools to allow for the assessment of the images and data. ViewPoint 6 is for professional use only and enables quick diagnostic reporting with standardized terminology. It has an intuitive graphical user interface (GUI) and is based on Microsoft Windows® with defined hardware requirements for the user to install on their computer. 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 - 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.
Intended Use/Indication 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.

Technology: The ViewPoint 6 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The proposed ViewPoint 6 system is substantially equivalent to the ViewPoint 6 (K173456) with regards to intended use, capabilities, technological characteristics, safety and effectiveness.

The proposed ViewPoint 6 is adding

- IOTA Classification ADNEX Model which was cleared with Voluson E10 (K192159).
- ACR TI-RADS Risk-stratification which was cleared in Versana Balance (K191792).
- Thyroid Nodule Overview Table comparison feature
- User defined section and fields

Summary of Non-Clinical Tests:

The ViewPoint 6 and its applications comply with voluntary standards:

- IEC 62366 - 1:2015 Medical devices-Application of usability engineering to medical devices
- IEC 62304:2006, Medical device software-Software life cycle process
- NEMA PS 3.1-3.20 (2016), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)
- ISO 14971:2012 Medical Devices-Application of risk management to medical devices
- IEC 82304-1:2016, Health software-General requirements for product safety

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews

- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Design Validation and Service Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, ViewPoint 6, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the ViewPoint 6 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.