DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

November 22, 2016

Re: K162743
Trade/Device Name: ViewPoint 6
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 28, 2016
Received: September 30, 2016

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162743

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.

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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

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

Date:	September 28, 2016
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 F:(414)918-8275
Secondary Contact Person:	Nadine Gebhard- Höflinger Regulatory Affairs GE Healthcare Austria GmbH & Co OG
Trade Name:	ViewPoint 6
Common/Usual Name:	PACS / Picture archiving and communications system
Classification Names:	Class II
Product Code:	Picture archiving and communications system, 21 CFR 892.2050, LLZ
Primary Predicate Device(s):	ViewPoint 6 (K103458)
Reference Predicate Device(s):	none
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. 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:

Indications for Use of ViewPoint 6

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:

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

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed ViewPoint 6 is substantially equivalent to the predicate ViewPoint 6 with regards to intended use, capabilities, technological characteristics, safety and effectiveness. There was no change in the indication for use.

Following changes were done compared to the predicate device:

- Distribution changed from physical DVD to an access controlled cloud based solution (e-distribution)
- Labelling updates made as needed to align with the product changes
- Expanded capabilities for image review/compare, measure, annotate, and adjust
- Added organization features – auto log off tracking, smartcard authentication, clinical scheduler, resource manager, spell check, code lists for billing, HL7 order management
- Added options for export of data and reports with an encrypted database
- Added adaptable lighting environment setting (lights-on/lights-off mode)
- Added workflow features for exam type definition, exam auto lock, multi-monitor support and new report forms

Summary of Non-Clinical Tests:

The ViewPoint 6 and its applications comply with voluntary standards:

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

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 proposed ViewPoint 6 to be as safe, as effective, and performance is substantially equivalent to the predicate device.