510(k) Summary

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

Date:	November 20, 2010
Submitter:	GE Healthcare [ViewPoint Bildverarbeitung GmbH] Argelsrieder Feld 12 Wessling, Germany, 82234 T: +49 8153 931191 F: +49 8153 931130
Primary Contact Person:	Nicole Landreville USA Premarket Regulatory Affairs Leader GE Healthcare, QARA Regions - Americas 3000 North Grandview Boulevard #W450 Waukesha, WI, USA, 53188 T: (289) 208-2365 F: (414) 918-4498
Secondary Contact Person:	Erich Zanner Site QA & Regulatory Affairs Leader GE Healthcare [ViewPoint Bildverarbeitung GmbH] Argelsrieder Feld 12 Wessling, Germany, 82234 T: +49 8153 931191 F: +49 8153 931130
Device/Trade Name:	ViewPoint 6
Common/Usual Name:	ViewPoint
Classification Names: Product Code:	PACS - Picture archiving and communications system LLZ, 892.2050
Predicate Device(s):	ViewPoint 5 [K050943]

Device Description:	GE ViewPoint 6 is an image archiving and reporting software for medical practices and clinical radiological departments used for diagnostic purpose. It incorporates basic features of nt administration, image and data acquisition from medical devices via DICOM or proprietary interface, data transfer from third party systems, reporting of medical findings, report generation, network interfacing and archiving. Image processing and calculations capabilities are available for images. The basis for this submission is a modification to a legally marketed device to incorporate additional features and to modify the wording of the indications for use statement for clarification purposes. The proposed indications for use statement is equivalent to the one from the predicate device. The intended use is identical to the predicate device. The device modifications mainly consist of: - Enhancements to the User Interface for improved usability; - Additional customization capabilities; - Configurable User Interface language.
Intended Use:	The GE ViewPoint is intended to accept, transfer, display, store and process medical images and data, including the ability to measure, calculate, annotate and prepare and print patient examination reports primarily for diagnostic ultrasound.
Technology:	The ViewPoint 6 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The ViewPoint 6 and its sub-applications comply with voluntary standards as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Performance testing (Verification) • Safety testing (Verification) • Simulated use testing (Validation) Summary of Clinical Tests: The subject of this premarket submission, ViewPoint 6, did not require clinical studies to support substantial equiva nce.
Conclusion:	GE Healthcare considers the ViewPoint 6 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

GE Healthcare
% Ms. Nicole Landreville
USA Premarket Regulatory Affairs Leader
3000 North Grandview Boulevard #W450
WAUKESHA WI 53188

MAR - 4 2011

Re: K103458
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: November 20, 2010
Received: December 20, 2010

Dear Ms. Landreville:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: ViewPoint 6

Indications for Use:

ViewPoint 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 provides the user the ability to including images, drawings, and charts into medical reports. ViewPoint 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 displays to the user, can be used for diagnostic purposes.

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

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

Prescription Use_X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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Prescription Use (Per 21 CFR 801.109)