K 110573
P 1/3

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

MAY - 3 2011

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

Date: February 25, 2011

Submitter: GE Healthcare (GE Medical Systems SCS)
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Device: Trade Name: READY View

Common/Usual Name: READY View

Classification Names: 21 CFR 892.2050 Picture archiving and communication system

Product Code: 90 LLZ

Predicate Device(s): FuncTool Option for Advantage Windows (K960265)
Volume Viewer Plus (K041521)

Device Description: READY View is a suite of applications developed to improve multi-parametric exams by enabling the analysis of MR generated data sets containing multiple images for each scan location. The MR data sets may be any of the following:

- A time series
- A diffusion weighted scan
- A diffusion tensor scan
- A variable echo imaging
- A blood oxygen level dependent imaging
- Spectroscopy (Single voxel and 2D or 3D CSI)

The READY View platform provides a combination of protocols, applications and tools that enables a fast, easy and quantified analysis of the multiple data sets.

Brain View is a post processing image analysis software package that provides advanced techniques to aid in the diagnosis of neurological and oncological diseases. Brain View is an option with the READY View platform and offers two advanced protocols:

- FiberTrak
- Arterial Spin Labeling (ASL)

READY View along with Brain View option is available on the Advantage Workstation (AW) and Advantage Workstation Server Gen 2, for viewing and processing Magnetic Resonance images.

Intended Use: READY View is an image analysis software that allows the user to process dynamic or functional volumetric data and to generate maps that display changes in image intensity over time, echo time, b-value (Diffusion imaging) and frequency (Spectroscopy). The combination of acquired images, reconstructed images, calculated parametric images, tissue segmentation, annotations and measurement performed by the clinician allows multi-parametric analysis and may provide clinically relevant information for diagnosis.

Technology:

READY View is a post-processing application processing MR functional data of the human body acquired from a MR Scanner. Targeted anatomy includes but is not limited to Brain, Breast, Prostate, and Liver.
Functional data sets contain a series of sequentially ordered images for each scan location, where the interval between images can represent time, b-value, echo time, gradient orientation or ppm value (frequency) depending on the data set.
The pixel value in an area of interest at a given scan location may have a different value for each image. To analyze these changes in pixel values, READY View provides two tools:

- Graphs: the pixel values at a given pixel location are plotted as a graph. The graphs can then be represented by the pixel value over the image number or the pixel value over time, b-value, echo time, gradient orientation or ppm value.
- Functional images: for each pixel location, the pixel values from the images are used to compute a characteristic parameter by means of a function. A functional map is then constructed by displaying the value of the parameter for each pixel location.

The READY View software employs the same algorithm technology as its predicate device FuncTool (K960265). Like FuncTool, READY View provides protocols that enable a fast, easy and quantified analysis of the multiple data sets.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The following quality assurance measures were applied to the development of READY View:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

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

Conclusion:

GE Healthcare considers READY View 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 (GE Medical Systems SCS)
% Ms. Elizabeth Mathew
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MAY - 3 2011

Re: K110573
Trade/Device Name: READY View
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 25, 2011
Received: March 1, 2011

Dear Ms. Mathew:

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 S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K110573

510(k) Number (if known): (INSERT 510(k) NUMBER IF KNOWN)
Device Name: READY View

Indications for Use

READY View is an image analysis software that allows the user to process dynamic or functional volumetric data and to generate maps that display changes in image intensity over time, echo time, b-value (Diffusion imaging) and frequency (Spectroscopy). The combination of acquired images, reconstructed images, calculated parametric images, tissue segmentation, annotations and measurement performed by the clinician allows multi-parametric analysis and may provide clinically relevant information for diagnosis.

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 In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k)_____

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K110573