K110919

Carestream

OCT 20 2011

Carestream Health Inc.
150 Verona Street
Rochester, NY 14608

"510(k) Summary"

510(k) Owner Name:	Carestream Health, Inc.
510(k) Owner Address:	150 Verona Street Rochester, New York 14608
510(k) Owner Phone:	585 627-6543
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Contact Name & Info:	John Pardo Director, Regulatory Affairs and Quality Systems John.pardo@carestreamhealth.com 585-627-6543
Date Summary Prepared:	7/15/2011
Device Trade Name:	Carestream PACS
Device Common Name:	PACS
Classification Name:	System, Image Processing, Radiological
Regulation Name:	Picture Archiving and Communication System
Device Class:	Class II
Device Code:	LLZ
Regulation Number:	21 CFR 892.2050
Predicate Device:	Carestream PACS Manufactured by Carestream Health, Inc. 510(k) No. – K083673 (December 30, 2008)

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Device Description:
CARESTREAM PACS is an image management system whose intended use is to provide completely scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems.

It is a software only solution that contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates the review, dictation and reporting tools that creates a productive work environment for the radiologists and physicians. It offers an intuitive user interface which includes a tab concept, grouping features, and functions with the same context together such as Image display, Monitor layout, Comparison, Wide area user tab, etc.

The device provides functionality to allow remote site access to image and patient data enabling diagnostic reading through industry standard interfaces. It is designed using an open architecture that allows for various proprietary and off the shelf software components to be integrated with off the shelf hardware components and configured meeting the user's specific needs in a single-site or multi-site environment.

Carestream PACS provides support for 3D registration of studies taken at different times or by different modalities for reading of CT/MRI or PET-CT images. The volumetric data sets are synchronized allowing the user to view reformatted series side by side and superimposed images. In all methods the algorithm is only using a rigid space transformation. Automatic vessel segmentation suggests a segmentation that that can either be accepted, ignored or fine tuned by the user.

The CARESTREAM PACS LightWeight Viewer feature addresses the need for a fast and simple web based tool to access patient records and images. It allows for high speed distribution of image data to users in a wide area setup. The software technology uses HTML5 which allows browser enabled devices to run the application without local software installation. The LightViewer has a simple GUI for viewing including zoom, pan, windowing, basic measurements, cine, etc.

The CARESTREAM PACS Lightweight Viewer provides wireless and portable access to medical images for referral purposes. It provides a diagnostic viewer of medical images substantially equivalent to the CARESTREAM PACS software, with portable device characteristics and functionality. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. The CARESTREAM PACS LightWeight Viewer software is not to be used for mammography in the US.

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The CARESTREAM PACS LightWeight Viewer operates on "off-the-shelf 'portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability, network dependencies, etc.). It is therefore required that the user follows the operating instructions and adhere to the risk mitigation guidelines.

CARESTREAM PACS does not drive or influence the use of the source device. It does not directly drive a decision regarding treatment or therapy without the intervention of subsidiary means. Images must be evaluated and the decision regarding treatment or therapy is determined by the user based on their standard procedures. CARESTREAM PACS is a complement to these standard procedures.

Intended Use:
The CARESTREAM PACS is an image management system whose intended use is to provide completely scaleable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems.

The system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates the review, dictation and reporting tools that creates a productive work environment for the radiologists and physicians.

The CARESTREAM PACS Lightweight Viewer software program is used for patient management by the referral community in order to access and display patient data, medical reports, and medical images from different modalities including CR, DR, CT, MR, NM and US after the primary reading has been completed on dedicated diagnostic workstations.

The CARESTREAM PACS Lightweight Viewer provides wireless and portable access to medical images for referral purposes. It is not intended to be used as, or to replace, a full diagnostic workstation or system and should be used only when there is no access to a workstation. This device is not to be used for mammography.

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Comparison of Technological Characteristics:
The modifications to the CARESTREAM PACS do not alter the fundamental scientific technology of the device. The only device modification was to the software. No new image manipulation tools are implemented that do not currently exist in the Carestream PACS device.

The differences in the Indication Statements between Carestream PACS and CARESTREAM PACS LightWeight Viewer describe specific restrictions on how CARESTREAM PACS LightWeight Viewer is to be used, given the hardware and portability differences between these two devices. CARESTREAM PACS LightWeight Viewer adds the explicate requirement that it should only be used when there is no access to a workstation, and that it is not to be used for mammography in the US.

Discussion of Testing
Performance testing was conducted to verify the design output met the design input requirements and to validate the device conformed to the defined user needs and intended uses. Testing was conducted under simulated use conditions. Predefined acceptance criteria was met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

Carestream Health conducted display performance testing using the CARESTREAM PACS Lightweight Viewer software on the iPad device. Testing measured contrast response and evaluated test patterns for luminosity, resolution, and noise according to IEC 62563-1 and AA PM TGI8 guidelines. Carestream Health also performed multiple studies with qualified radiologists using a variety of modalities, specifically CR, DR, CT, MR, NM and US under different environmental conditions. Results of these studies affirm the diagnostic image viewing capabilities of CARESTREAM PACS LightWeight Viewer when used as indicated.

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

OCT 20 2011

Mr. John Pardo
Senior Director, Regulatory Affairs and Quality Systems
Carestream Health, Inc.
150 Vernon Street
ROCHESTER NY 14608

Re: K110919
Trade/Device Name: CARESTREAM PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 29, 2011
Received: September 30, 2011

Dear Mr. Pardo:

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

Statement of Intended Use

510(k) Number (if known): K110919

Device Name: CARESTREAM PACS

Indications for Use:
The CARESTREAM PACS is an image management system whose intended use is to provide completely scaleable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems.

The system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates the review, dictation and reporting tools that creates a productive work environment for the radiologists and physicians.

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Prescription Use____X____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (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)

Mary S. Pastel

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

510K K110919