K023673

"510(k) Summary"

DEC 30 2008

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:	Linda Stewart Regulatory Affairs Director, Medical Imaging linda.stewart@carestreamhealth.com 972-517-1481
Date Summary Prepared:	November 26, 2008
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:	Mirada Solutions Ltd, Fusion 7D Manufactured by Siemens Medical Solutions, Inc 510(k) No. - K020546 (April 26, 2002)

Device Description:

Carestream PACS, a multi-modality radiology reading and reporting station, provides support for 3D registration of studies taken at different times or by different modalities (CT and MRI), and for reading 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.

The registration in the "Volume Matching" application can be created by these methods:

- Register Studies
  Full Automatic registration: The user is able to register two datasets by simply clicking on the windows that present these datasets, with no other additional input. The algorithm will not take into account the exact clicking points.
- Manually Register Studies
  The user is able to "manually" register two datasets by providing additional inputs to the registration algorithm. The matching of the two volumes is done based on the planes of the two studies and on the position of the two clicking points. This input should be enough to match the two dataset. The user should try to click on the same anatomical location in both studies, while both planes are already swiveled to represent the same anatomical plane.
- Refine Registration
  The user is able to adjust the registration. The refine algorithm is actually a local registration algorithm that tries to match two volumes based on local, rather than global, similarity. Practically, it can serve the user when he/she wants to focus on a certain region and to compare it in the two datasets. In such cases, local registration is preferable, even if it means that the global registration will be of a poorer quality.
- Treat Studies as Registered
  The application supports the "treat studies as registered" feature – the ability for the user to select datasets / all datasets for which the system should treat as if they are fully registered to one another. This is needed to support places where although the data doesn't have the same frame of reference, they were registered in a "black-box" and only then copied to the PACS. The algorithm is ignoring the exact clicking point.

Reading PET-CT images require both specific image-manipulation capabilities and standardized uptake value presentation. PET scanning utilizes a radioactive molecule that is similar to glucose, called fluorodeoxyglucose (FDG). FDG accumulates within malignant cells because of their high rate of glucose metabolism, and is currently the radiotracer most commonly used for PET imaging.

The standardized uptake value (SUV) is a semi-quantitative value that allows expression of FDG uptake in a lesion relative to the injected dose. The

standardized uptake value (SUV) is defined as the ratio of activity in tissue per millimeter to the activity in the injected dose per patient body weight.

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.

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 exist in the Fusion7D device. The device modifications raise no new issues of safety or effectiveness.

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. Nonclinical 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 2008

Ms. Linda Stewart
Regulatory Affairs Director, Medical Imaging
Carestream Health, Inc.
150 Verona Street
ROCHESTER NY 14608

Re: K083673
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: December 9, 2008
Received: December 11, 2008

Dear Ms. Stewart:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K083673

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.

Prescription Use____X____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices