APR 0 1 2014

K140271
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Carestream

Carestream Health Inc.
150 Verona Street
Rochester, NY 14608

510(k) Summary Pursuant to 21 CFR 807.92

510(k) Owner Name:	Carestream Health, Inc.
510(k) Owner Address:	150 Verona Street Rochester, New York 14608
510(k) Owner Phone:	585-627-8790
510(k) Owner Fax:	585-323-7643
Contact Name & Info:	Alexandra Chamberlain Regulatory Affairs Manager alexandra.chamberlain@carestream.com 585-627-8790
Date Summary Prepared:	January 31, 2014
Device Trade Name:	Tablet Viewer Software for Image Suite
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:	Image Suite Manufactured by Carestream Health, Inc. 510(k) Number – K100094 (March 11, 2010)

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Device Description:

CARESTREAM Tablet Viewer Software for Image Suite is an optional feature for Image Suite Mini-PACS users. The software technology uses HTML5 which allows a browser-enabled mobile device to run the software application. The user is able to access patient images and study reports from an iPad 2 mobile device anywhere through a wireless network. Tablet Viewer Software for Image Suite has a simple GUI for viewing and includes some fundamental tools such as zoom, pan, windowing, basic measurements, cine, etc. Tablet Viewer Software for Image Suite functions as an extension to Image Suite.

CARESTREAM Image Suite is a stand-alone, self-contained radiographic imaging system designed to provide a low-cost platform to manage medical images, reports, patient/exam information and workflow in small clinics. The system performs capture, processing, review, archive, and printing of radiographic images as well as report writing and printing and is designed to run on a PC workstation. CARESTREAM Image Suite is designed to be simple and intuitive to both use and service.

CARESTREAM Image Suite connects with hardware including multiple radiographic image capture devices (CR and / or DR detectors) attached to a PC workstation with either a standard or a high-resolution monitor. CARESTREAM Image Suite is designed as a hardware-independent system and may be interfaced with verified and validated imaging modalities from both Carestream Health and 3rd party vendors, as well as Carestream Health PACS systems, and other 3rd party PACS systems. The Image Suite system can directly acquire an image from Carestream Health acquisition devices and is PC and monitor independent.

Indications for Use:

CARESTREAM Image Suite is an image management system whose intended use is to receive, process, review, display, print and archive images and data from all imaging modalities.

Tablet Viewer Software for Image Suite is used for patient management by clinicians in order to access and display patient data, medical reports, and medical images for diagnosis from different modalities including CR, DR, CT, MR, and US.

Tablet Viewer Software for Image Suite provides wireless and portable access to medical images for remote reading or referral purposes from web browsers including usage with validated mobile devices. This device is not intended to replace the full Mini-PACS and should be used only when there is no access to the full Mini-PACS Web Viewer.

This excludes mammography applications in the United States.

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Technological Characteristics:

The Tablet Viewer Software for Image Suite is fully compatible with Image Suite and can be displayed on the iPad 2 mobile device.

The product is software, and has been extensively tested in accordance with *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*. The product is DICOM Compliant. Testing included the following:

- Bench testing on the Apple iPad 2 for luminance response, optimal viewing angles, resolution, noise, reflectivity, device and display settings, and exception handling
- A Clinical Assessment of Tablet Viewer Software for Image Suite on the Apple iPad 2
- Functional QA testing of the software

The technological characteristics of the new device are equivalent to the predicate device in that they use the same Image Suite PACS platform. The new type of display device is being introduced by the introduction of Tablet Viewer Software for Image Suite.

The Indications of the predicate and subject are similar, differing only by the added description related to the remote access from the validated mobile device and the list of supported modalities for the Tablet Viewer software.

Substantial Equivalence:

Tablet Viewer Software for Image Suite is a new feature that can be used with Image Suite (predicate device, K100094). The software provides wireless and portable access to medical images for remote reading or referral purposes using an iPad 2 mobile device. Results of bench and clinical testing demonstrated that the Tablet Viewer Software for Image Suite is suitable as a platform to display patient data, medical reports, and medical images for diagnosis from different modalities including CR, DR, CT, MR, and US. No substantial differences that affect safety and efficacy were noted in comparison with the predicate device.

Conclusion:

CARESTREAM Tablet Viewer Software for Image Suite is substantially equivalent to the CARESTREAM Image Suite predicate. The product has been validated and tested and no substantial differences that affect safety and efficacy were noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 1, 2014

Carestream Health, Inc.
% Ms Alexandra Chamberlain
Regulatory Affairs Manager
150 Verona Street
ROCHESTER NY 14608

Re: K140271
Trade/Device Name: Tablet Viewer Software for Image Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 4, 2014
Received: February 5, 2014

Dear Ms Chamberlain:

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.

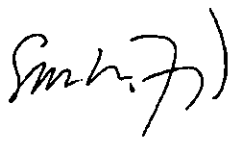
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140271

Device Name
CARESTREAM Tablet Viewer Software for Image Suite

Indications for Use *(Describe)*

CARESTREAM Image Suite is an image management system whose intended use is to receive, process, review, display, print and archive images and data from all imaging modalities.

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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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*