DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Carestream Health, Inc.
% Ms. Carolyn Wagner
Sr. Manager of Regulatory Affairs and Quality Systems
150 Verona Street
ROCHESTER NY 14608

September 21, 2015

Re: K151774
Trade/Device Name: Carestream Vue Motion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 24, 2015
Received: August 25, 2015

Dear Ms. Wagner:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

Robert Ochs, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151774

Device Name
CARESTREAM Vue Motion

Indications for Use *(Describe)*

The Vue Motion software program is used for patient management by clinicians in order to access and display patient data, medical reports, medical data, and medical images for diagnosis from different modalities including CR, DR, CT, MR, NM, ECG, and US.

Vue Motion 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 full workstations and should be used only when there is no access to a workstation. For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by FDA for mammography.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Carestream

"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:	585-627-6588
510(k) Owner Fax:	585-323-7643
Contact Person & Info:	Carolyn Wagner Sr. Manager, Regulatory Affairs and Quality Systems carolyn.wagner@carestreamhealth.com 585-627-6588
Date Summary Prepared:	August 23, 2015
Device Trade Name:	CARESTREAM Vue Motion
Device Common Name:	System, image processing, radiological
Classification Name:	Picture archiving and communications system
Device Class:	Class II
Device Code:	LLZ
Regulation Number:	21 CFR 892.2050
Predicate Devices:	CARESTREAM Vue Motion Manufactured by Carestream Health, Inc. 510(k) No. – K132824 (February 6, 2014) Primary Predicate McKesson Cardiology™ ECG Mobile Manufactured by McKesson Israel Ltd. 510(k) No. – K133534 (April 18, 2014) Secondary Predicate

Device Description:
CARESTREAM Vue Motion with ECG Feature is a Light Viewer designed to provide wireless and portable access to medical images for remote reading or referral purposes from web browsers including enterprise distribution of radiology images and related data.

The modification to the Vue Motion device described in this submission includes the addition of software to facilitate display of ECG data. The modified Vue Motion device with ECG display capability raises no new issues of safety or effectiveness.

Indications for Use / Intended Use:
The Indications for Use for the modified device, as described in its labeling, are:
"The Vue Motion software program is used for patient management by clinicians in order to access and display patient data, medical reports, medical data, and medical images for diagnosis from different modalities including CR, DR, CT, MR, NM, ECG, and US.

Vue Motion 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 full workstations and should be used only when there is no access to a workstation. For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by FDA for mammography."

The intended use for the modified device, as determined by descriptions and the proposed labeling contained in this submission, is similar to the Indications for Use statement provided above. The new ECG display is a dedicated application for displaying ECG waveform data and exam details.

The ECG display feature described in this submission results in a minor modification to the Indications For Use to add ECG as an additional modality from which medical data can be displayed.

Comparison of Technological Characteristics:
Based upon information provided within this submission, we believe that the CARESTREAM Vue Motion with ECG display feature is substantially equivalent to the legally marketed CARESTREAM Vue Motion (without ECG feature) and to the McKesson Cardiology™ ECG Mobile (predicate devices).

The modified Vue Motion (with ECG capability) and the legally marketed Vue Motion cleared under K132824 have the same intended use except that the modified device has been updated to include capability to display ECG data received in DICOM format. This is reflected in the change to the Indications for Use statement to list ECG along with the other display capabilities.

The modified Vue Motion device offers the same functionality as the K132824 Vue Motion device with the addition of the ECG display capability. In addition, the 3D viewing capabilities described in K132824 for the PACS device (K132824) are now also included on Vue Motion. These features do not function any differently on Vue Motion than on the PACS. All other major viewing functions available on Vue Motion remain unchanged.

The modified Vue Motion (with ECG capability) and the legally marketed McKesson Cardiology™ ECG Mobile predicate device have the same intended use, noting that the predicate device contains additional intended use beyond

what Vue Motion provides. Any variation in features or technical specifications have been identified and addressed through testing (described below) to support a substantial equivalence determination. More specifically, both devices:

- View ECG test results, such as waveforms, synopsis measurements and diagnosis statements from the acquisition device.
- View the ECG lead traces using different display settings.
- Compare the results of current ECG tests with any previous ECG test results stored on the PACS.
- Perform ECG-related measurements.
- Provide secure access to ECG records and related information.
- Require a Wi-Fi connection when displayed on a tablet device. (McKesson Cardiology™ ECG Mobile can also require a cellular connection.)
- Do not store ECG or patient related information on the mobile device.
- Do not communicate directly with cardiographs or other waveform acquisition devices.
- Do not use any automatic electronic data processing or pattern recognition methods to derive measurement or provide diagnostic statements from the ECG data.
- Do not allow modification of the original ECG traces (waveforms) stored on the PACS.
- Are not intended for real time monitoring.
- Can be used both inside and outside of medical facilities except areas where wireless device use is prohibited. (For McKesson Cardiology ECG Mobile, the same applies to a cellular connection.)

The modifications to the CARESTREAM Vue Motion do not alter the fundamental scientific technology of the device.

Discussion of Testing:
The performance characteristics and operation / usability of the modified Vue Motion application (with ECG capability) were evaluated in non-clinical (bench) testing. Non-clinical testing performed included software verification, validation, and security testing to ensure that Vue Motion with ECG feature met all product / design requirements. Accuracy of the ECG capabilities was verified in a simulated user test environment by comparing the sample waveform data, patient information, and measurement information obtained from the source data to what was displayed and measured using Vue Motion.

In all instances, the Vue Motion application functioned as intended by the product / design requirements, and the observed results demonstrated substantial equivalence to the predicate device.

Substantial Equivalence:
The proposed primary predicate device, CARESTREAM Vue Motion, has been found substantially equivalent by FDA through the 510(k) process (K132824) and is legally marketed. Its Indications for Use are exactly the same as the proposed Indications for Use for the modified Vue Motion device, except for

the addition of ECG (Electrocardiogram) as a modality from which data can be displayed. Its Indications for Use, though not identical to the modified Vue Motion's, convey similar information about the intended use of the device and can therefore be considered for substantial equivalence.

The proposed predicate device, McKesson Cardiology™ ECG Mobile, has been found substantially equivalent by FDA through the 510(k) process (K133534) and is legally marketed. Its Indications for Use, though not identical to the modified Vue Motion's, convey similar information about the intended use of the device and can therefore be considered for substantial equivalence.

The differences between the Vue Motion with ECG Display feature and the predicate devices do not affect the intended use of the device or alter the fundamental scientific technology of the device. Performance test results support a substantial equivalence determination of the Vue Motion with ECG Display feature to the Vue Motion device cleared under K132824 and to the McKesson Cardiology™ ECG Mobile cleared under K133534.