



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

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

February 12, 2016

Re: K153103
Trade/Device Name: CARESTREAM Vue PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 11, 2016
Received: January 13, 2016

Dear Ms. Koetter:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. A large, faint "FDA" watermark is visible in the background behind the signature.

FOR

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153103

Device Name

CARESTREAM Vue PACS

Indications for Use (Describe)

“The CARESTREAM Vue 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.

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

The system contains a Perfusion module with interactive tools to ease the process of analyzing and comparing Computed Tomography Perfusion (CTP) images of adult patients. The Arterial Input Function (AIF), Venous Output Function (VOF), and Brain Centerline are automatically detected with the ability for manual correction by the user. Blood perfusion parameters are automatically calculated and displayed as a set of user friendly perfusion maps and perfusion tables summarizing the results. The perfusion maps include relative Cerebral Blood Volume (rCBV), relative Cerebral Blood Flow (rCBF), Mean Transit Time (MTT), Time to Peak (TTP), and Time to maximum impulse response function (TMAX). The perfusion tables include the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

The system supports Subtraction with interactive tools to aid with the analysis of Digital Subtraction Angiography (DSA) images in both interventional radiology and cardiology. Subtraction automatically subtracts a mask from contrast frames of an X-Ray Angiography study for visualization of vascular anatomy and pathology of adult patients.

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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“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: 585-627-6505
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Contact Person & Info: Diane Koetter
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Systems
diane.koetter@carestream.com
585-627-6505

Date Summary Prepared: January 8, 2016

Device Trade Name: CARESTREAM Vue PACS
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: Olea Sphere
Manufactured by Olea Medical
510(k) No. – K120196 (April 19, 2012)

Olea Sphere v2.3
Manufactured by Olea Medical
510(k) No. – K132095 (December 26, 2013)

Philips Easy Vision Family Workstation Option
Vascular Analysis
Manufactured by Philips Medical Systems, Inc.
510(k) No. – K973835 (January 6, 1998)

Device Description:

CARESTREAM Vue PACS is an image management system. It provides functionality to allow remote site access to image and patient data enabling diagnostic reading through industry standard interfaces. The modification to the Vue PACS device described in this submission includes the addition of the following modules:

1. Perfusion Module – The calculation of parameters related to tissue flow (perfusion) and tissue blood volume.
2. Subtraction Feature – Subtraction of two images representing the same part of the anatomy (one with contrast media and one without contrast media) resulting in an image that displays the vascular anatomy/pathology only.

Indications for Use / Intended Use:

The Indications for Use for the modified device, as described in its labeling, are: “The CARESTREAM Vue 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.

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

The system contains a Perfusion module with interactive tools to ease the process of analyzing and comparing Computed Tomography Perfusion (CTP) images of adult patients. The Arterial Input Function (AIF), Venous Output Function (VOF), and Brain Centerline are automatically detected with the ability for manual correction by the user. Blood perfusion parameters are automatically calculated and displayed as a set of user friendly perfusion maps and perfusion tables summarizing the results. The perfusion maps include relative Cerebral Blood Volume (rCBV), relative Cerebral Blood Flow (rCBF), Mean Transit Time (MTT), Time to Peak (TTP), and Time to maximum impulse response function (TMAX). The perfusion tables include the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

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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 Indications for Use for the subject device is the same as for the predicate devices and the intended use remains unchanged. Any variation in features or technical specifications have been identified and addressed through testing (described below) to support a substantial equivalence determination.

Comparison of Technological Characteristics:

Based upon information provided within this submission, we believe that the CARESTREAM Vue PACS Perfusion Module and Subtraction Feature are substantially equivalent to the legally marketed Olea Sphere Perfusion Module and Philips EasyVision Family Workstation Option Vascular Analysis (predicate devices) respectively.

Carestream Vue PACS Perfusion Module and Olea Sphere Perfusion Module both:

- Provide a Perfusion plug-in to compute optimized parametric maps (rCBV, rCBF, TTP, MTT, TMAX, TMIP) from raw perfusion series
- Provide automatic or manual Arterial Input Function (AIP)
- Provide automatic or manual Venous Output Function (VOF)
- Provide background segmentation
- Support various deconvolution methods/algorithms
- Support motion correction to minimize motion artifacts
- Calculate lesion and hypoperfused volumes

The investigational device differs from the predicate device in that investigational device supports an additional method for the generation of the perfusion maps.

Carestream Vue PACS Subtraction Feature and Philips Easy Vision Family Workstation Option Vascular Analysis both:

- Support the post-processing, or Subtraction, on DSA images
- Subtract an image without contrast from image(s) without contrast
- Apply pixel shifting to correct motion

The investigational device differs from the predicate device in that it does not support Run Subtraction which is supported by the predicate device. The predicate device has additional pixel shifting methods which are not supported by the investigational device.

Discussion of Testing:

The imaging performance of Carestream Vue PACS Subtraction Feature was validated through Engineering Tests that demonstrated Subtraction was applied correctly to both X-Ray Angiography (XA) test pattern and XA clinical images for all grey shades and boundary conditions using both quantitative and visual tests. In all instances, the Vue PACS Subtraction Feature functioned as intended and the observed results demonstrated substantial equivalence to the Philips Easy Vision Family Workstation Option Vascular Analysis (predicate device).

The imaging performance of the Carestream Vue PACS Perfusion Module (investigational device) was compared with the Olea Sphere Perfusion Module (predicate device) in a clinical study. The purpose of the study was to demonstrate equivalent clinical quality between the investigational and predicate devices using a radiologist evaluation of key metrics which are applicable to CTP images. The results of this study demonstrated substantial equivalence to the predicate device.

Substantial Equivalence:

The proposed predicate devices, Olea Sphere Perfusion Module (K120196) and Olea Sphere v2.3 (K132095), have been found substantially equivalent by FDA through the 510(k) process and are legally marketed. Their Indications for Use, though not identical to the modified Carestream Vue PACS Perfusion Module, convey similar information about the intended use of the devices and can therefore be considered for substantial equivalence. Clinical studies verified equivalent clinical quality between the investigational and predicate devices demonstrating a substantial equivalence determination.

The predicate devices provide an additional algorithmic option for generation of the perfusion maps. This does not affect the clinical use of the investigational device as several other algorithms are supported by the predicate and investigational devices.

The proposed predicate device, Philips Easy Vision Family Workstation Option Vascular Analysis has been found substantially equivalent by FDA through the 510(k) process (K973835) and is legally marketed. Its Indications for Use, though not identical to the modified Carestream Vue PACS Subtraction Feature, convey similar information about the intended use of the device and can therefore be considered for substantial equivalence. Engineering Tests validated the Vue PACS Subtraction Feature functioned as intended and the observed results demonstrated substantial equivalence to the predicate device.

The predicate device provides additional options to aid in the visualization of

the subtracted images; this does not have any impact on the subtraction or clinical use of the product.