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

April 11, 2017

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

Re: K170580
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: February 17, 2017
Received: February 28, 2017

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,

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

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)*
K170580

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 is to be used by trained professionals including, but not limited to, physicians and medical technicians.

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 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 analyze and compare Computed Tomography Perfusion (CTP) and MR Perfusion (MRP) images of adult patients. Blood perfusion parameters are automatically calculated and displayed as a set of perfusion maps and perfusion tables. The perfusion tables include the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

The system contains a Diffusion Module with interactive tools to ease the process of analyzing and comparing MR Diffusion Weighted images (DWI) and MR Diffusion Tensor Imaging (DTI) of adult patients. This module is used to visualize local water diffusion properties from the analysis of diffusion- weighted MRI data.

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."

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:	585-627-6505
510(k) Owner Fax:	585-627-8802
Contact Person & Info:	Diane Koetter Sr. Manager, Regulatory Affairs and Quality Systems diane.koetter@carestream.com 585-627-6505

Date Summary Prepared:	February 17, 2017
Device Trade Name:	Carestream Vue PACS
Device Common Name:	System, image processing, radiological
Classification Name:	Picture archiving and communications system
Device Class:	2
Device Code:	*LLZ*
Regulation Number:	21 CFR 892.2050
Predicate Device:	Olea Sphere v3.0 Manufactured by: Olea Medical 510(k) No.: K152602 (March 3, 2016)

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 system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images.

The modification to the Vue PACS device described in this submission includes the addition of the MR Perfusion and Diffusion Module.

Indications for Use / Intended Use:

The Indications for Use for the 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 is to be used by trained professionals including, but not limited to, physicians and medical technicians.

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 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 analyze and compare Computed Tomography Perfusion (CTP) and MR Perfusion (MRP) images of adult patients. Blood perfusion parameters are automatically calculated and displayed as a set of perfusion maps and perfusion tables. The perfusion tables include the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

The system contains a Diffusion Module with interactive tools to ease the process of analyzing and comparing MR Diffusion Weighted images (DWI) and MR Diffusion Tensor Imaging (DTI) of adult patients. This module is used to visualize local water diffusion properties from the analysis of diffusion- weighted MRI data.

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 intended use for this device, as determined by descriptions and the proposed labeling contained in this submission, is similar to the Indications for Use statement provided above.

The Indications for Use for the subject device is similar to the predicate device 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 is substantially equivalent to the legally marketed Olea Sphere v3.0 Perfusion and Diffusion Modules (predicate device).

Comparison of the investigational and predicate devices:

- Both devices provide a Perfusion plug-in to compute optimized rCBV, rCBF, TTP, MTT, TMAX, and TMIP parametric maps from raw perfusion series.
- Both devices provide automatic or manual Arterial Input Function (AIF).
- Both devices provide automatic or manual Venous Output Function (VOF).
- Both devices provide background segmentation, where the hypoperfused and lesion tissues are calculated based upon AIF and VOF.
- Both devices support sSVD (standard singular value decomposition), cSVD (blockcirculant singular value decomposition), and oSVD (oscillation singular value decomposition) deconvolution methods/algorithms for generation of the perfusion maps.
- Both devices support motion correction to minimize motion artifacts when generating the perfusion maps.
- Both devices calculate lesion and hypoperfused volumes based upon parameters and values supplied by the user.
- The predicate device differs from the investigational device in that it supports a Bayesian deconvolution methods/algorithms for generation of the perfusion maps, while the investigational device does not.
- Both devices support the ADC map for Diffusion Weighted Imaging.
- Both devices support map display for Diffusion Tensor Imaging of the following types Fractional Anisotropy (FA), Relative Anisotropy (RA), Volume Ratio (VR), ADC/Mean Diffusivity (ADC), Axial Diffusivity (AD), and Relative Diffusivity (RD).

Discussion of Testing

The performance characteristics and operation / usability of the Carestream Vue PACS MR Perfusion and Diffusion Module were evaluated in non-clinical (bench) testing. These studies have demonstrated the intended workflow, related performance, overall function, shipping performance, verification and validation of requirements for intended use, and reliability of the system including both software and hardware requirements. Non-clinical test results have demonstrated that the device conforms to its specifications. Predefined acceptance criteria were met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

A Clinical study was performed to establish substantial equivalence for the Carestream Vue PACS MR Perfusion and Diffusion Module to its predicate, the Olea Sphere V3.0. The objective of this study was to compare the similarity of the parametric maps of MR DSC-Perfusion (Perfusion Module), MR DWI (Diffusion Module) and MR DTI (Diffusion Module) in Carestream Vue PACS ("investigational device") to the Olea Sphere PACS with Perfusion and DWI Modules ("predicate device"). The results of this study demonstrated substantial equivalence in the similarity of the parametric maps of the Carestream Vue PACS MR Perfusion and Diffusion module as compared with the Olea Sphere V3.0.