Canon Medical Systems Corporation
Paul Biggins
Director Regulatory Affairs
2441 Michelle Drive
TUSTIN, CA 92780

November 26, 2018

Re: K183013
Trade/Device Name: Vitrea Software Package, VSTP-001A
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, IYN, IYL
Dated: October 30, 2018
Received: October 31, 2018

Dear Paul Biggins:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183013

Device Name

Vitrea Software Package; VSTP-001A

Indications for Use *(Describe)*

Vitrea Software Package is an application package developed for use on Vitrea®, a medical diagnostic system that allows the processing, review, analysis, communication and media interchanges of multidimensional digital images acquired from a variety of imaging devices. Vitrea has the following indications:

The CT/XA Cerebral Artery Morphological Analysis application is intended to facilitate the extraction and segmentation of user identified aneurysms on the cerebral arteries. The software can be used as an adjunct to diagnosis for the purposes of measurement of size and aspect ratio.

The MR Wall Motion Tracking application is intended to assist physicians with performing cardiac functional analysis based upon magnetic resonance images. It provides measurements of global and regional myocardial function that is used for patients with suspected heart disease.

The MR Coronary Tracking application is intended to assist physicians with performing coronary artery analysis for MR heart images which are intended for the qualitative and quantitative analysis of coronary arteries.

The SUREVolume Synthesis application is intended to load volume images acquired by whole-body X-ray CT scanners, X-ray angiography systems, and MRI systems and displays fusion images.

The Angio Viewer application displays image data acquired using an X-ray angiography system. It supports cine display, subtraction, and distance measurement.

The US Cardiac Fusion application enables fusion display of the analysis results obtained using the US 3D Wall Motion Tracking application and the CT Coronary Artery Analysis application.

The Ultrasound Clinical Applications are indicated for the visualization of structures, and dynamic processes with the human body using saved ultrasound DICOM images to provide image information for diagnosis.

Embolization Plan is a post processing software that is intended to assist physicians in the visualization of the liver arterial tree using 3D images of CT or 3D images of Cone Beam CT acquired by Toshiba or Canon Medical Systems. It provides tools to assist the user in analysis of these images. The output is intended to be an adjunct means that allows automatic and manual planning of the liver arterial vessels for guidance of the embolization procedure. The output is a 3D visualization of the hepatic arteries to high dense lesion in the liver.

The DE Stone Analysis application is intended to serve as an adjunct visualization tool for the differentiation between uric acid and non-uric acid stones greater than 3mm with Dual Energy CT studies.

The DE Composition Analysis application is intended to serve as an adjunct visualization tool for the uric acid presence within surrounding anatomical structures with Dual Energy CT studies.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K183013

1. **SUBMITTER'S NAME**
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   1385 Shimoishigami
   Otawara-Shi, Tochigi-ken, Japan 324-8550

2. **OFFICIAL CORRESPONDENT**
   Naofumi Watanabe
   Senior Manager, Regulatory Affairs and Vigilance

3. **ESTABLISHMENT REGISTRATION**
   9614698

4. **CONTACT PERSON**
   Paul Biggins
   Senior Director Regulatory Affairs
   Canon Medical Systems USA, Inc.
   2441 Michelle Drive
   Tustin, CA 92780
   (714) 669-7808 (voice)

5. **DATE PREPARED**
   September 20, 2018

6. **TRADE NAME(S)**
   Vitrea Software Package, VSTP-001A

7. **COMMON NAME**
   Radiological Image Processing Software

8. **DEVICE CLASSIFICATION**
   Class II (per 21 CFR 892.2050, Picture Archiving and Communications System)

9. **PRODUCT CODE/DESCRIPTION**
   90LLZ / Picture Archiving and Communications System

10. **PERFORMANCE STANDARD:** None

11. **PREDICATE DEVICES**

Application	Predicate	510(k) Control#	Status
MR Wall Motion Tracking	VSTP-001A	K151093	Cleared
Cerebral Aneurysm Analysis (CT/XA Cerebral Artery Morphological Analysis)	VSTP-001A	K151093	Cleared
MR Coronary Tracking	VSTP-001A	K171222	Cleared
SURE Volume Synthesis	VSTP-001A	K173088	Cleared

Angio Viewer	VSTP-001A	K173088	Cleared
US Cardiac Fusion	VSTP-001A	K173088	Cleared
Ultrasound Application Package	VSTP-001A	K180323	Cleared
Application	Predicate	510(K) Control #	Status
Dual Energy Stone Analysis	Canon Aquilion	K132813	New
Dual Energy Composition Analysis	Canon Aquilion	K132813	New
Embolization Planning Tool	Philips EmboGuide	K142273	New

Primary Predicate Device: VSTP-001A, K180323
Reference Predicate Device: Canon Aquilion ONE; K132813[1]
Reference Predicate Device: Philips EmboGuide; K142273[2]

12. REASON FOR SUBMISSION

Modification - Porting of application software (DE) from a different class device[1].
Implementation of a new software application (Embolization Planning)[2].

13. DEVICE DESCRIPTION

Vitrea Software Package, VSTP-001A, an application package developed for use on Vitrea, a medical image processing software, marketed by Vital Images, Inc. Vitrea Software Package, VSTP-001A, currently includes ten post processing applications, MR Wall Motion Tracking, Cerebral Aneurysm Analysis, MR Coronary Tracking, Sure Volume Synthesis, Angio Viewer, US Cardiac Fusion, Ultrasound Applications Package, Dual Energy Stone Analysis, Dual Energy Composition Analysis and Embolization Planning which use brain, body or cardiac image data, obtained from CT/XA/MR/US systems, to assist physicians in performing specialized measurements and analysis.

14. INDICATIONS FOR USE

Vitrea Software Package is an application package developed for use on Vitrea®, a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea has the following additional indications:

The Cerebral Aneurysm Analysis application is intended to facilitate the extraction and segmentation of user identified aneurysms on the cerebral arteries. The software can be used as an adjunct to diagnosis for the purposes of measurement of size and aspect ratio.

The MR Wall Motion Tracking application is intended to assist physicians with performing cardiac functional analysis based upon magnetic resonance images. It provides measurements of global and regional myocardial function that is used for patients with suspected heart disease.

The MR Coronary Tracking application is intended to assist physicians with performing coronary artery analysis for MR heart images which are intended for the

qualitative and quantitative analysis of coronary arteries.

The SUREVolume Synthesis application is intended to load volume images acquired by whole-body X-ray CT scanners, X-ray angiography systems, and MRI systems and displays fusion images.

The Angio Viewer application displays image data acquired using an X-ray angiography system. It supports cine display, subtraction, and distance measurement.

The US Cardiac Fusion application enables fusion display of the analysis results obtained using the US 3D Wall Motion Tracking application and the CT Coronary Artery Analysis application.

The Ultrasound Clinical Applications are indicated for the visualization of structures, and dynamic processes with the human body using saved ultrasound DICOM images to provide image information for diagnosis.

The DE Stone Analysis application is intended to serve as an adjunct visualization tool for the differentiation between uric acid and non-uric acid stones greater than 3 mm with Dual Energy CT studies.

The DE Composition Analysis application is intended to serve as an adjunct visualization tool for the uric acid presence within surrounding anatomical structures with Dual Energy CT studies.

Embolization Plan is a post processing software that is intended to assist physicians in the visualization of the liver arterial tree using 3D images of CT or 3D images of Cone Beam CT (INFX-8000 Interventional Family) acquired by Toshiba or Canon Medical Systems. It provides tools to assist the user in analysis of these images. The output is intended to be an adjunct means that allows automatic and manual planning of the liver arterial vessels for guidance of the embolization procedure. The output is a 3D visualization of the hepatic arteries to high dense lesion in the liver.

15. SUBSTANTIAL EQUIVALANCE

The Dual Energy software applications included in the Vitrea Software Package, VSTP-001A, perform in a manner similar to and are intended for the same use (image processing) as the previously cleared Aquilion Dual Energy Software. The Dual Energay applicatons utilize the same formulas, algorithms and measurements as found on the predicate device. The porting of this software to the Vitrea Workstation required modifications to the GUI and acquiring images from the Vitrea Image Database (DiCOM). The subject and predicated devices are all post processing applications that are used to aid physicians with performing measurement and analysis of diagnotic images.

A complete comparison table for this application is included in this submission. See below for a brief comparison summary of technological characteristics of the devices:

Dual Energy Stone Analysis

Item	Vitrea Software Package: DE Stone Analysis	Aquilion Dual Energy System Package
	(Subject Device)	(K132813)
Intended Use	This software is intended to serve as an adjunct visualization tool for the differentiation between uric acid and non-uric acid stones greater than 3mm with Dual Energy CT studies.	The Dual Energy System allows the system to acquire two CT images of the same anatomical location using distinct tube voltages and/or tube currents during two tube rotations. The x-ray dose will be the sum of the dose of each tube rotation at its respective tube voltage and current. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in x-ray attenuation between these distinct energies. This information may also be used to reconstruct images at multiple energies within the available spectrum, and to reconstruct basis images that allow the visualization and analysis of anatomical and pathological materials. The visualization of the differentiation between uric acid and non-uric acid stones greater than 3mm and the visualization of uric acid presence within surrounding anatomical structures is provided with the Dual Energy system. When used by a qualified physician, a potential application is to determine the course of treatment. Performance of this device may be affected by body size and motion artifacts.
Anatomical Region	whole body	whole body

Feature	- Image Processing ・Visualization of the differentiation between uric acid and non-uric acid stones	- Scanning the same anatomical location using distinct tube voltages and/or tube currents - Reconstruction of images at multiple energies and basis images ・Iodine Map ・Monochromatic - Image Processing ・Visualization of the differentiation between Uric Acid and non-uric acid stones ・Visualization of uric acid concentrations within surrounding anatomical structure
Image data format for image processing	DICOM format of CT image data	Original format of CT image data
	MPR	MPR / 3D (MPR in DE Stone Analysis)
Segmentation	The region included in the range of set CT numbers is extracted.	・The region included in the range of set CT numbers is extracted. ・The compositions is extracted based on the composition setting.

Dual Energy Composition Analysis

Item	Vitrea Software Package: DE Composition Analysis	Aquilion Dual Energy System Package
	(Subject Device)	(K132813)
Intended Use	This software is intended to serve as an adjunct visualization tool for the uric acid presence within surrounding anatomical structures with Dual Energy CT studies.	The Dual Energy System allows the system to acquire two CT images of the same anatomical location using distinct tube voltages and/or tube currents during two tube rotations. The x-ray dose will be the sum of the dose of each tube rotation at its respective tube voltage and current. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in x-ray attenuation between these distinct energies. This information may also be used to reconstruct images at multiple energies within the available

		spectrum, and to reconstruct basis images that allow the visualization and analysis of anatomical and pathological materials. The visualization of the differentiation between uric acid and non-uric acid stones greater than 3mm and the visualization of uric acid presence within surrounding anatomical structures is provided with the Dual Energy system. When used by a qualified physician, a potential application is to determine the course of treatment. Performance of this device may be affected by body size and motion artifacts.
Anatomical Region	whole body	whole body
Feature	- Image Processing ・Visualization of uric acid presence within surrounding anatomical structures	- Scanning the same anatomical location using distinct tube voltages and/or tube currents - Reconstruction of images at multiple energies and basis images ・Iodine Map ・Monochromatic - Image Processing ・Visualization of the differentiation between Uric Acid and non-uric acid stones ・Visualization of uric acid concentrations within surrounding anatomical structure
Image data format for image processing	DICOM format of CT image data	Original format of CT image data
	MPR /3D	MPR / 3D (MPR/3D in DE Composition Analysis)
Segmentation	The compositions is extracted based on the composition setting.	・The region included in the range of set CT numbers is extracted. ・The compositions is extracted based on the composition setting.

Embolization Plan

The Embolization Plan software application included in the VSTP-001A software has the same intended use as the Philips EmboGuide software. Both software applications use DICOM format images obtained using a 3D acquisition serve as an adjunct tool to assist the clinician in determining the feeder vessels during an embolization procedure. The main difference between the two software applications is the inclusion of the ability to use DICOM data and CBCT data on the subject device compared to CBCT data only for the predicate device.

A complete comparison table for this application is included in this submission. See below for a brief comparison summary of technological characteristics of the devices

Item	Embolization Plan	EmboGuide
	(Subject Device)	(K142273)
Intended Use	Embolization Plan is a post processing software that is intended to assist physicians in the visualization of the liver arterial tree using 3D images of CT or 3D images of Cone Beam CT acquired by Toshiba or Canon Medical Systems. It provides tools to assist the user in analysis of these images. The output is intended to be an adjunct means that allows automatic and manual planning of the liver arterial vessels for guidance of the embolization procedure. The output is a 3D visualization of the hepatic arteries to high dense lesion in the liver.	EmboGuide is a post processing software medical device intended to assist physicians in performing embolization of hypervascular tumors in the liver using interventional X-ray. It provides tools to help the user with the analysis of 3D rotational angiography images. Its output is intended as an adjunct means to help with the planning and guidance of the embolization procedure. It provides real time overlay of 3D rotational angiography images on live 2D X-ray images of the same anatomy to support device/catheter guidance.
Anatomical region	liver	liver
Input	CT / CBCT	CBCT
	MPR / 3D	MPR / 3D
Vessel tracking	automatic manual	automatic manual
Distance	manual	manual

16. SAFETY

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC62304 and IEC62366.

17. TESTING

The Dual Energy was subject to risk analysis and regression testing that was conducted through bench testing which are included in this submission to demonstrate that the requirements for the applications have been met. Bench studies were conducted using sample data sets from the predicate device verification activities (K131823) and verifying that the outputs for both devices were substantially the same.

The embolization plan was verified using sample data that was obtained from clinical institutions where local ethical controls were in place. The data was reviewed and verified independently by a test group and a control group. The resulting performance data demonstrated that the software was effective in assisting clinicians to identify the required feeder vessels for embolization planning.

This device is not subject to Cybersecurity Requirements as it has no access to an outside environment. All images being queued by the VSTP-001A are resident on the host Vitrea platform. The host Vitrea platform conducts all external data transactions and the Cybersecurity documentation is included for the Vitrea.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document” issued on May 11, 2005, is also included as part of this submission.

18. CONSLUSION

The software applications included in the Vitrea Software Package, VSTP-001A, perform in a manner similar to and are intended for the same use as the predicate device Based upon this information, conformance to standards, successful completion of software validation, application of risk management and design controls and the performance data presented in this submission it is concluded that the subject device is substantially equivalent in safety and effectiveness to the predicate devices.