Canon Medical Systems Corporation
% Orlando Tadeo, Jr.
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
TUSTIN CA 92780

February 16, 2021

Re: K203312
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
Dated: January 27, 2021
Received: January 28, 2021

Dear Mr. Tadeo:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203312

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 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 Spectral 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 Spectral CT studies acquired on the Canon Medical Systems scanner.

The Spectral Composition Analysis application is intended to assist a physician in visualizing the presence of monosodium urate in anatomical structures. The clinical syndrome of gout is characterized by the presence of monosodium urate crystals in joints or soft tissue.

The Embolization Plan application 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 Spectral Analysis application is a CT, non-invasive image analysis software package, which may be used to aid in the visualization of anatomical and pathological materials. The software provides quantification of Hounsfield units of iodine

attenuation differences and iodine concentration and display by color.

Effective Z and Electron Density maps may aid in the differentiation and characterization of different tissues in the human body.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K203312

510(k) Summary

1. **SUBMITTER'S NAME**
   Fumiaki Teshima
   Sr. Manager, Quality Assurance Department
   Canon Medical Systems Corporation
   1385 Shimoishigami
   Otawara-Shi, Tochigi-ken, Japan 324-8550

2. **ESTABLISHMENT REGISTRATION**
   9614698

3. **OFFICIAL CORRESPONDENT/CONTACT PERSON**
   Orlando Tadeo, Jr.
   Sr. Manager, Regulatory Affairs Department
   Canon Medical Systems USA, Inc.
   2441 Michelle Dr.
   Tustin, CA 92780
   (714) 669-7459

4. **DATE PREPARED**
   November 06, 2020

5. **DEVICE NAME(S)**
   Vitrea Software Package, VSTP-001A

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)
   Picture Archiving and Communications Systems – Product Code: 90LLZ [per 21 CFR 892.2050]

9. **PREDICATE DEVICE**

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
Vitrea Software Package, VSTP-001A*	Canon Medical Systems, USA	21 CFR 892.2050	Picture Archiving and Communications System	LLZ	K192923	10/15/2019

** Includes: MR Wall Motion Tracking, Cerebral Aneurysm Analysis, (CT/XA Cerebral Artery Morphological Analysis), MR Coronary Tracking, SURE Volume Synthesis, Angio Viewer, US Cardiac Fusion, Ultrasound Applications Package, Dual Energy Stone Analysis, Dual Energy Composition Analysis, Embolization Planning Tool*

10. REASON FOR SUBMISSION

Modification of an existing medical device.

11. DEVICE DESCRIPTION

Vitrea Software Package, VSTP-001A, is 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, SUREVolume Synthesis, Angio Viewer, US Cardiac Fusion, Ultrasound Applications Package, Dual Energy Stone Analysis, Dual Energy Composition Analysis and Embolization Planning Tool which use brain, body or cardiac image data, obtained from CT/XA/MR/US systems, to assist physicians in performing specialized measurements and analysis.

12. 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 Spectral 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 Spectral CT studies acquired on the Canon Medical Systems scanner.

The Spectral Composition Analysis application is intended to assist a physician in visualizing the presence of monosodium urate in anatomical structures. The clinical syndrome of gout is characterized by the presence of monosodium urate crystals in joints or soft tissue.

The Embolization Plan application 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 Spectral Analysis application is a CT, non-invasive image analysis software package, which may be used to aid in the visualization of anatomical and pathological materials. The software provides quantification of Hounsfield units of iodine attenuation differences and iodine concentration and display by color.

Effective Z and Electron Density maps may aid in the differentiation and characterization of different tissues in the human body.

13. SUBSTANTIAL EQUIVALANCE

The **Vitrea Software Package, VSTP-001A**, is substantially equivalent to and has the same intended use as the primary predicate device, which received premarket clearance under K192923, and is marketed by Canon Medical Systems USA. The changes being made to the existing device are the modfiication of three applications, Spectral Stone Analysis, Spectral Composition Analysis and Spectral Analysis. The modifications to these three applications were evaluated by risk analysis and a regression review, and it was determined that they were implemented with all risks reduced to an acceptable level.

Item	**Vitrea Software Package, VSTP-001A (V8.8)**	**Vitrea Software Package, VSTP-001A (V8.5)**
510(k) Number	**(Subject Device)**	**K192923**
Anatomical region	Whole body	Whole body
Type of Input Data	Acquired by spectral scan (TSX-306A/3, V10.3 or earlier and V10.4 and later)	Acquired by spectral scan (TSX-306A/3, V10.3 or earlier)
	Spectral Stone Analysis • Monochromatic images Spectral Composition Analysis • Basis material images and monochromatic image Spectral Analysis • Basis material images and monochromatic image	Spectral Stone Analysis • Monochromatic images Spectral Composition Analysis • Basis material images and monochromatic image Spectral Analysis • Basis material images and monochromatic image
Type of Output Data	Spectral Stone Analysis • Analysis result display • Secondary capture (RGB image) Spectral Composition Analysis • Analysis result display • Secondary capture (RGB image) • Batch MPR and DICOM volume save	Spectral Stone Analysis • Analysis result display • Secondary capture (RGB image) Spectral Composition Analysis • Analysis result display • Secondary capture (RGB image)

Item	Vitrea Software Package, VSTP-001A (V8.8)	Vitrea Software Package, VSTP-001A (V8.5)
510(k) Number	**(Subject Device)**	**K192923**
	Spectral Analysis • Analysis result display • Secondary capture (RGB image) • Batch MPR and DICOM volume save	Spectral Analysis • Analysis result display • Secondary capture (RGB image)
Image Processing	Spectral Stone Analysis • Visualization of the differentiation between uric acid and non-uric acid stones Spectral Composition Analysis • Visualization of monosodium urate presence within surrounding anatomical structures Spectral Analysis • Generation of monochromatic images (ranging from 35keV – 200keV) o Smoothing filter • Generation of Iodine map • VNC image • Generation of Electron Density Image • Generation of Effective Z Image • Generation of Basis material image (bone/water)	Spectral Stone Analysis • Visualization of the differentiation between uric acid and non-uric acid stones Spectral Composition Analysis • Visualization of monosodium urate presence within surrounding anatomical structures Spectral Analysis • Generation of monochromatic images (ranging from 35keV – 135keV) • Generation of Iodine map • VNC image • Generation of Electron Density Image • Generation of Effective Z Image
Analysis	**Segmentation**	
	Spectral Stone Analysis • The region included in the range of set CT numbers is extracted. Spectral Composition Analysis • The compositions are extracted based on the composition setting.	Spectral Stone Analysis • The region included in the range of set CT numbers is extracted. Spectral Composition Analysis • The compositions are extracted based on the composition setting.
	Spectral Analysis • Monochromatic image o Basis material dual energy analysis • Iodine map o Three material decomposition • Electron density o Basis material dual energy analysis • Effective Z o Basis material dual energy analysis • Basis material image (bone/water) o Basis material dual energy analysis	Spectral Analysis • Monochromatic image o Basis material dual energy analysis • Iodine map o Three material decomposition • Electron density o Basis material dual energy analysis • Effective Z o Basis material dual energy analysis

Item	Vitrea Software Package, VSTP-001A (V8.8)	Vitrea Software Package, VSTP-001A (V8.5)
510(k) Number	**(Subject Device)**	**K192923**
Display	Spectral Stone Analysis* • MPR Spectral Composition Analysis • MPR, 3D Spectral Analysis • MPR, Fusion image, MIP image, MinIP image, Displaying three MPR planes	Spectral Stone Analysis • MPR Spectral Composition Analysis • MPR, 3D Spectral Analysis • MPR, Fusion image

**Color Display Function in Spectral Stone Analysis was updated, for the Material Line Preset label to list only "Uric Acid" and "Non Uric Acid*

14. 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 IEC60601-1-6.

15. TESTING

Risk analysis and verification/validation activities conducted through bench testing which is included in this submission demonstrate that the established specifications for the device have been met. Additional performance testing, using phantom studies, were conducted to assess the improvements to existing features. A physician review of clinical images was also performed, in order to support a new promotional claim for the previously cleared Spectral Analysis feature, specifically, that spectral iodine maps are designed to assist physicians in visualizing iodine differences in the lung. Results of all these studies demonstrate that the features included in this submission meet specifications and perform as intended.
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 referenced for this submission.

16. CYBERSECURITY

The Vitrea Software Package, VSTP-001A is a portfolio of software applications developed by Canon that are integrated into the Vital Images Vitrea workstations. As such this software has no connections to the internet, wired or wireless networks, etc. All import and export of data is within the domain of the Vital product. Based upon this information it should be noted that CyberSecurity requirements do not apply to this device.

17. CONCLUSION

The software applications modified 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 device, Vitrea Software Package, VSTP-001A, 510(k) cleared per K192923.