June 16, 2022

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

Re: K213504
Trade/Device Name: Aquilion ONE (TSX-306A/3) V10.12 with Spectral Imaging System, Vitrea Software Package, VSTP-001A
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK, LLZ
Dated: May 12, 2022
Received: May 13, 2022

Dear Orlando 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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological Imaging and Electronic Products
OHT8: Office of 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)*

K213504

Device Name

Aquilion ONE (TSX-306A/3) V10.12 with Spectral Imaging System

Indications for Use *(Describe)*

This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head, with the capability to image whole organs in a single rotation. Whole organs include, but are not limited to brain, heart, pancreas, etc.

The Aquilion ONE has the capability to provide volume sets of the entire organ. These volume sets can be used to perform specialized studies, using indicated software/hardware, of the whole organ by a trained and qualified physician.

FIRST is an iterative reconstruction algorithm intended to reduce exposure dose and improve high contrast spatial resolution for abdomen, pelvis, chest, cardiac, extremities and head applications.

AiCE is a noise reduction algorithm that improves image quality and reduces image noise by employing Deep Convolutional Neural Network methods for abdomen, pelvis, lung, cardiac, brain, inner ear and extremities applications.

The spectral imaging system utilizes two scan modes, spectral imaging scan and dual energy scan.

The spectral imaging scan allows the system to acquire two nearly simultaneous CT images of an anatomical location using distinct tube voltages and/or tube currents by rapid KV switching. The X-ray dose will be the sum of the dose at each respective tube voltage and current in a rotation.
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.

The dual energy scan, utilized for brain imaging, 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. Performance of dual energy scan may be affected by body size and motion artifacts.

When used by a qualified physician, a potential application is to determine the course of treatment

PIQE is a Deep Learning Reconstruction method designed to enhance spatial resolution. By incorporating noise reduction into the Deep Convolutional Neural Network (DCNN), it is possible to achieve both spatial resolution improvement and noise reduction for cardiac applications.

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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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213504

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Effective Z and Electron Density maps may aid in the differentiation and characterization of different tissues in the human body.

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510(k) SUMMARY **K213504**

1. SUBMITTER'S NAME:

Fumiaki Teshima
Senior 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
Canon Medical Systems USA, Inc
2441 Michelle Drive
Tustin, CA 92780
(714) 669-7459

4. DATE PREPARED:

October 28, 2021

5. TRADE NAME(S):

Aquilion ONE (TSX-306A/3) V10.12 with Spectral Imaging System

6. COMMON NAME:

Computed Tomography X-ray System

7. DEVICE CLASSIFICATION:

a) Classification Name: Computed Tomography X-ray system
b) Regulation Number: 21 CFR §892.1750
c) Regulatory Class: Class II

8. PRODUCT CODE:

JAK

9. PERFORMANCE STANDARD:

This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR, Subchapter J, Part 1020]

10. PREDICATE DEVICE:

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
Primary: Aquilion ONE (TSX-306A/3) V10.4 with Spectral Imaging System	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K203225	03/24/2021

11. REASON FOR SUBMISSION:

Modification of existing medical device

12. DEVICE DESCRIPTION:

Aquilion ONE (TSX-306A/3) V10.12 with Spectral Imaging System is a whole body multi-slice helical CT scanner, consisting of a gantry, couch and a console used for data processing and display. This device captures cross sectional volume data sets used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician. This system is based upon the technology and materials of previously marketed Canon CT systems.

13. INDICATIONS FOR USE:

This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head, with the capability to image whole organs in a single rotation. Whole organs include, but are not limited to brain, heart, pancreas, etc.

The Aquilion ONE has the capability to provide volume sets of the entire organ. These volume sets can be used to perform specialized studies, using indicated software/hardware, of the whole organ by a trained and qualified physician.

FIRST is an iterative reconstruction algorithm intended to reduce exposure dose and improve high contrast spatial resolution for abdomen, pelvis, chest, cardiac, extremities and head applications.

AiCE is a noise reduction algorithm that improves image quality and reduces image noise by employing Deep Convolutional Neural Network methods for abdomen, pelvis, lung, cardiac, brain, inner ear and extremities applications.

The spectral imaging system utilizes two scan modes, spectral imaging scan and dual energy scan.

The spectral imaging scan allows the system to acquire two nearly simultaneous CT images of an anatomical location using distinct tube voltages and/or tube currents by rapid KV switching. The X-ray dose will be the sum of the dose at each respective tube voltage and current in a rotation. 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.

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anatomical and pathological materials. Performance of dual energy scan may be affected by body size and motion artifacts.

When used by a qualified physician, a potential application is to determine the course of treatment

PIQE is a Deep Learning Reconstruction method designed to enhance spatial resolution. By incorporating noise reduction into the Deep Convolutional Neural Network (DCNN), it is possible to achieve both spatial resolution improvement and noise reduction for cardiac applications.

14. SUBSTANTIAL EQUIVALENCE:

The **Aquilion ONE (TSX-306A/3) V10.12 with Spectral Imaging System** is substantially equivalent to **Aquilion ONE (TSX-306A/3) V10.4 with Spectral Imaging System**, which received premarket clearance under K203225, and is marketed by Canon Medical Systems USA. The intended use of the Aquilion ONE is the same as that of the predicate device. The **Aquilion ONE (TSX-306A/3) V10.12 with Spectral Imaging System** includes changes made to the predicate device including implementation of PIQE (Precise IQ Engine), brain imaging for Spectral Imaging System, SilverBeam Filter, increased maximum couch-top speed, and a console with a new intuitive user interface. A comparison of the technological characteristics between the subject and the predicate device is included below.

	Subject Device	**Predicate Device**	**Comment**
Device Name, Model Number	**Aquilion ONE (TSX-306A/3) V10.12 with Spectral Imaging System**	**Aquilion ONE (TSX-306A/3) V10.4 with Spectral Imaging System**	
510(k) Number	**This submission**	**K203225**	
Reconstruction	PIQE (Precision IQ Engine)	AIDR 3D	PIQE is a Deep Learning Reconstruction algorithm that improves spatial resolution and noise reduction
• Scan Region	Cardiac	Whole Body	
• Scan Types	Volume, Dynamic Volume	Volume, Dynamic Volume, Helical	
• Spectral Scan	Not Available	Available	
• Reconstruction Interval	0.25* and 0.5 mm	Can be set in increments of a minimum of 0.1 mm	* When double slice kit is installed
Magnified Reconstruction	Min. 70 mm Max. 500 mm	No restriction on the minimum Max. 500 mm	
Wedge Filter Types	M, L, SilverBeam Filter	M, L	
Couch-top Speed	0.8 - 300 mm/s (315 kg) 0.8 - 160 mm/s (220 kg)	0.8 - 200 mm/s (315 kg) 0.8 - 160 mm/s (220 kg)	

	Subject Device	Predicate Device	Comment
Device Name, Model Number	**Aquilion ONE (TSX-306A/3) V10.12 with Spectral Imaging System**	**Aquilion ONE (TSX-306A/3) V10.4 with Spectral Imaging System**	
510(k) Number	**This submission**	**K203225**	
Spectral Imaging System • Scan Type • Scan Regions	Available -Rapid kV Switching and Dual Energy Scan (Brain) -Abdomen and pelvis, Chest, Extremities, Cardiac and Brain	Available -Rapid kV Switching -Abdomen and pelvis, Chest, Extremities and Cardiac	
Console Upgrade with new user interface (CGS-102A)	Available*	Not Available	*: System software version after CGS-102A is installed is V1.1. This kit cannot be used in combination with V10.12.

15. 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 following standards IEC60601-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-6, IEC60601-1-9, IEC60601-2-28, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, NEMA XR-25, NEMA XR-26 and NEMA XR-29. Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR, Subchapter J, Part 1020]

16. TESTING

Risk analysis and verification/validation activities conducted through bench testing demonstrate that the established specifications for the device have been met.

Performance Testing - Bench

PIQE Image Quality Evaluation

CT image quality metrics were performed, utilizing phantoms, to assess Contrast-to-Noise Ratios (CNR), CT Number Accuracy, Uniformity, Slice Sensitivity Profile (SSP), Modulation Transfer Function (MTF)-Wire, Modulation Transfer Function (MTF)-Edge, Standard Deviation of Noise (SD), Noise Power Spectra (NPS), Low Contrast Detectability (LCD) and Pediatric imaging. It was concluded that PIQE is substantially equivalent to the predicate device as demonstrated by the results of the above testing.

PIQE Spatial Resolution

A phantom study was conducted and the subject device demonstrated 8 lp/cm greater high contrast spatial resolution compared to AIDR 3D.

Other PIQE evaluation studies, using various phantoms, were conducted to support the following claims:

- Reduced noise compared to AIDR 3D
- Improved Off-Center Resolution compared to AIDR 3D
- Improved signal/object visualization for the most common cardiac tasks compared to AIDR 3D
- Reduced noise without loss of noise texture compared to AIDR 3D
- Improved spatial resolution and simultaneously reduced noise compared to AIDR 3D
- Improved CT number accuracy for fine structures compared to AIDR 3D
- Improved CNR in all planes compared to AIDR 3D

SilverBeam Image Quality Evaluation

CT image quality metrics were performed utilizing phantoms, to assess the performance of SilverBeam over a range of fixed techniques applicable to lung cancer screening compared to the predicate device, with regard to the following metrics: Contrast-to-Noise Ratios (CNR), CT Number Accuracy, Uniformity, Slice Sensitivity Profile (SSP), Modulation Transfer Function (MTF)-Edge, Standard Deviation of Noise (SD), Noise Power Spectra (NPS), and Low Contrast Detectability (LCD). It was concluded that the subject device demonstrated equivalent or improved performance, compared to the predicate device, as demonstrated by the results of the above testing.

SilverBeam Dose Reduction

A phantom study was conducted which compared dose in Head/Body modes between normal scan mode and in DR-mode (with SilverBeam Filter) and it was determined that DR-mode resulted in dose reduction.

3D Scanogram

A study was conducted utilizing water and anthropomorphic phantoms and the subject device demonstrated the ability to produce substantially equivalent 3D and 2D scanongrams.

Performance Testing – Clinical Images

Representative body, cardiac, low dose chest and head diagnostic images, reviewed by an American Board Certified Radiologist, were obtained using the subject device and it was confirmed that the reconstructed images using the subject device were of diagnostic quality.

A summary of the risk analysis and verification/validation testing conducted through bench and clinical testing is included in this submission which demonstrates that the requirements for the system have been met.

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 included in TAB 7 of this submission. This documentation includes justification for the Moderate Level of Concern determination as well as testing which demonstrates that the verification and validation requirements for the modifications described above have been met.

A Software Information Checklist is included at the conclusion of this Executive Summary.

Cybersecurity documentation, per the FDA cybersecurity premarket guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices " issued on October 2, 2014, is also included as part of this submission.

17. CONCLUSION

The **Aquilion ONE (TSX-306A/3) V10.12 with Spectral Imaging System** performs in a manner similar to and is intended for the same use as the predicate device, as indicated in product labeling. 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 has demonstrated substantial equivalence to the predicate device and is safe and effective for its intended use.

K213504

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

4. **DATE PREPARED**
   October 27, 2021

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, Medical Image Management and Processing System)
   Medical Image Management and Processing System – Product Code: LLZ [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 *(Primary Predicate)*	Canon Medical Systems, USA	21 CFR 892.2050	Medical Image Management and Processing System	LLZ	K203312	02/16/2021

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
Aquilion ONE (TSX-306A/3) V10.4 with Spectral Imaging System *(Reference Predicate)*	Canon Medical Systems, USA	21 CFR 892.1750	Computed Tomography X-ray system	JAK	K203225	03/24/2021

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 eleven post processing applications, MR Wall Motion Tracking, Cerebral Aneurysm Analysis, MR Coronary Tracking, SUREVolume Synthesis, Angio Viewer, US Cardiac Fusion, Ultrasound Applications Package, Spectral Stone Analysis, Spectral Composition Analysis, Embolization Planning Tool and Spectral Analysis 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:

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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 K203312, and is marketed by Canon Medical Systems USA. The changes being made to the existing device include modfiications of the Spectral Analysis feature. The modifications 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 (8.10)	Vitrea Software Package, VSTP-001A (V8.8)	Comment
510(k) Number	**Subject Device**	**K203312**	
Anatomical region	Whole body	Whole body	No change
Type of Input Data	Acquired by spectral scan (TSX-306A/3, V10.11 or earlier and V10.12 and later)	Acquired by spectral scan (TSX-306A/3, V10.3 or earlier and V10.4 and later)	
	Spectral Analysis • Basis material images and monochromatic image o Dual Energy scan (AiCE Brain reconstruction* o Segmentation Data derived from* ▪ Vitrea CT Myocardial Perfusion ▪ Vitrea Coronary Artery Analysis	Spectral Analysis • Basis material images and monochromatic image	*New
Type of Output Data	Spectral Analysis • Analysis result display • Secondary capture (RGB image) • Batch MPR and DICOM volume save	Spectral Analysis • Analysis result display • Secondary capture (RGB image) • Batch MPR and DICOM volume save	No change
Image Processing	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 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)	No change

Item	Vitrea Software Package, VSTP-001A (8.10)	Vitrea Software Package, VSTP-001A (V8.8)	Comment
510(k) Number	**Subject Device**	**K203312**	

Analysis	Spectral Analysis
	• Monochromatic image
	  ○ Basis material dual energy analysis
	• Iodine map
	  ○ Three material decomposition
	• Electron density
	  ○ Basis material dual energy analysis
	• Effective Z
	  ○ Basis material dual energy analysis
	• Basis material image (bone/water)
	Basis material dual energy analysis
		Spectral Analysis
		• Monochromatic image
		  ○ Basis material dual energy analysis
		• Iodine map
		  ○ Three material decomposition
		• Electron density
		  ○ Basis material dual energy analysis
		• Effective Z
		  ○ Basis material dual energy analysis
		• Basis material image (bone/water)
		Basis material dual energy analysis
			No change

Display	• MPR, Fusion image, MIP image, MinIP image, Displaying three MPR planes,
	• New:
	  ○ 3D*
	  ○ Chamber View*
	  ○ Polar map*
	  ○ Curved Planar Reconstruction (CPR)*
	  ○ Stretched Planar Reconstruction (SPR)*
	  ○ Crosscut*
	  ○ Fusion to CPR/SPR* and Crosscut*
		MPR, Fusion image, MIP image, MinIP image, Displaying three MPR planes	* New

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. 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 as for this submission.

16. CYBERSECURITY

The 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.