Canon Medical Systems Corporation
% Orlando Tadeo Jr.
Sr. Manager, Regulatory Affairs
Canon Medical Systems, USA
2441 Michelle Drive
Tustin, California 92780

July 17, 2024

Re: K240705
Trade/Device Name: Vitrea Software Package, VSTP-002A V2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 10, 2024
Received: June 10, 2024

Dear Orlando Tadeo Jr.:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240705

Device Name

Vitrea Software Package, VSTP-002A V2.0

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 Software Package has the following additional indications:

Auto MPR Brain application is a post processing software of CT brain images that is intended to align images into a standard anatomical position for review. It provides tools to reformat images parallel to a standard anatomical position.

Subtraction Viewer is a viewer application that is intended for viewing original, subtraction and fusion CT images, but such subtraction processing is not a part of this application. This application supports fusion display of original image and subtraction image generated by other 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.

510(k) Summary

1. **SUBMITTER'S NAME**
   Fumiaki Teshima
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   Canon Medical Systems Corporation
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2. **ESTABLISHMENT REGISTRATION**
   9614698

3. **OFFICIAL CORRESPONDENT/CONTACT PERSON**
   Orlando Tadeo, Jr.
   Sr. Manager, Regulatory Affairs
   Canon Medical Systems USA, Inc.
   2441 Michelle Dr.
   Tustin, CA 92780
   (714) 483-1551

4. **DATE PREPARED**
   March 14, 2024

5. **DEVICE NAME(S)**
   Vitrea Software Package, VSTP-002A V2.0

6. **TRADE NAME(S)**
   Vitrea Software Package, VSTP-002A V2.0

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-002A (Primary Predicate)	Canon Medical Systems USA, Inc.	21 CFR §892.2050	Medical Image Management and Processing System	LLZ	K223336	01/09/2023
Aquilion ONE (TSX-305A/3) V8.3 with FIRST 2.1, SURE Subtraction Iodine Mapping (Reference Predicate)	Canon Medical Systems USA, Inc.	21 CFR §892.1750	Computed Tomography X-ray System	JAK	K170177	06/30/2017

10. REASON FOR SUBMISSION

Modification of a cleared device

11. DEVICE DESCRIPTION

The Vitrea Software Package, VSTP-002A V2.0, is a portfolio of applications software designed to be used in the Canon Medical Informatics Vitrea workstation. VSTP-002A currently includes post processing applications, Auto MPR Brain and Subtraction Viewer, which use CT image data, obtained from Canon CT Systems, to assist physicians in performing specialized measurements and analysis.

Auto MPR Brain is a software application that aligns CT brain images into a standard anatomical position for review.

Subtraction Viewer, also marketed as SCT Viewer, is a software application intended to view original, subtraction and fusion CT images. This application supports fusion display of original images and subtraction images generated by other applications and includes the ability to adjust fusion rate and ROI measurements of fusion images.

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 Software Package has the following additional indications:

Auto MPR Brain application is a post processing software of CT brain images that is intended to align images into a standard anatomical position for review. It provides tools to reformat images parallel to a standard anatomical position.

Subtraction Viewer is a viewer application that is intended for viewing original, subtraction and fusion CT images, but such subtraction processing is not a part of this application. This application supports fusion display of original image and subtraction image generated by other applications.

13. SUBSTANTIAL EQUIVALANCE

The Vitrea Software Package, VSTP-002A V2.0, perform in a manner similar to and are intended for the same use as Vitrea Software Package, VSTP-002A, 510(k) cleared per K223336. Both are 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. The software application, Subtraction Viewer, included in Vitrea Software Package, VSTP-002A V2.0, performs in a manner similar to and is intended for the same use as Vitrea Software Package, VSTP-002A, 510(k) cleared per K223336. Both are post processing software used to view original, subtraction and fusion CT images. See below for a brief comparison of the technological characteristics between the subject and the predicate device:

	Subject Device	Predicate Device	Reference Predicate Device
Device Name, Model Number	Vitrea Software Package, VSTP-002A V2.0	Vitrea Software Package, VSTP-002A	Aquilion ONE (TSX-305A/3) V8.3 with FIRST 2.1, SURESubtraction Iodine Mapping
510(k) Number	This Submission	K223336	K170177
Auto MPR Brain	Available	Available	N/A
Subtraction Viewer	Available	Available	Available
- Anatomical region	Whole Body	Whole Body	Abdomen
- Type of input data	CT image (Both of CE, nonCE and subtraction image derived from SURESubtraction applications)	CT image (Both of CE, nonCE and subtraction image derived from SURESubtraction applications)	CT image (both of CE and nonCE images)
- Type of output data	- Secondary capture (RGB) - CE Boost image	- Secondary capture (RGB)	- Secondary capture (RGB) - CE Boost image - Subtraction image
- Main Feature	- Display subtraction images (color fusion and gray scale fusion) ○ Fusion display: Yes ○ Change fusion ratio: Yes - Generate CE Boost image and display ○ Change of filter level: Yes	- Display subtraction images (color fusion and gray scale fusion) ○ Fusion display: Yes ○ Change fusion ratio: Yes	- Display subtraction images (color fusion and gray scale fusion) ○ Fusion display: Yes ○ Change fusion ratio: Yes - Generate CE Boost image and display ○ Change of filter level: No - Subtraction process between CE and nonCE images.

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, IEC60601-1-6, IEC62366-1, ISO15223-1, and ISO20417.

15. TESTING

Risk analysis and verification/validation testing conducted through bench testing are included in this submission which demonstrates that the requirements for the application have been met.

Performance Testing - Bench

- Evaluation of CE Boost Contrast-to-Noise Ratio The performance of the Subtraction Viewer software was evaluated using images of adult cases derived from a Canon CT scanner. These cases included abdomen, brain, neck, chest, pulmonary embolism, and limb scans. It was confirmed that the CE Boost images have a higher CNR than the CE image, and the CNR of these images increases with the CE Boost level.

  A Basic Documentation Level was determined, per the FDA guidance document, “Content of Premarket Submissions for Device Software Functions” issued on June 14, 2023, is also included as part of this submission.

16. CYBERSECURITY

The VSTP-002A is a portfolio of software applications developed by Canon that are integrated into the Canon Medical Informatics Vitrea workstations. The Vitrea workstation includes all cybersecurity controls and is responsible for importing images into an internal database. The software applications included in VSTP-002A pulls applicable images from the Vitrea directory to be processed and then places the processed images back into the directory within Vitrea. 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 Canon Medical Informatics product.

17. CONCLUSION

The Vitrea Software Package, VSTP-002A V2.0, intended use of the subject device is unchanged from that of the predicate device and testing demonstrates that the modifications to the subject device did not impact the performance or intended use compared to 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 has demonstrated substantial equivalence to the predicate devices and is as safe and effective for its intended use.