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

Re: K223336 January 9, 2023
Trade/Device Name: Vitrea Software Package, VSTP-002A
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 17, 2022
Received: November 17, 2022

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,

Jessica Lamb

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223336

Device Name

Vitrea Software Package, VSTP-002A

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 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.

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 K223336

1. **SUBMITTER'S NAME**
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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**
   October 31, 2022

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

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

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: 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 (Primary Predicate)	Canon Medical Systems USA	21 CFR §892.2050	Medical Image Management and Processing System	LLZ	K213504	2/16/2021
CT CoPilot (Reference Predicate)	ZepMed, LLC.	21 CFR §892.2050	Medical Image Management and Processing System	LLZ	K161322	12/07/2016

10. REASON FOR SUBMISSION

New software application

11. DEVICE DESCRIPTION

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

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

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 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.

13. SUBSTANTIAL EQUIVALANCE

The Vitrea Software Package, VSTP-002A, perform in a manner similar to and are intended for the same use as VSTP-001A, 510(k) cleared per K213504. 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, Auto MPR, included in Vitrea Software Package, VSTP-002A, performs in a manner similar to and is intended for the same use as CT CoPilot, 510(k) cleared per K161322. Both are post processing software used to provide auto reformatting for standard viewing of CT brain images and are intended to automate the current manual process of image alignment. See below for a brief comparison of the technological characteristics between the subject and the predicate device:

	Subject	Primary Predicate	Reference Predicate
Device Name	Vitrea Software Package (VSTP-002A) V1.0	Vitrea Software Package (VSTP-001A) V8.10	CT CoPilot
Available Applications	Auto MPR	Cerebral Aneurysm Analysis, MR Wall Motion Tracking, MR Coronary Tracking, SUREVolume Synthesis, Angio Viewer, US Cardiac Fusion, Ultrasound Clinical Applications, Spectral Stone Analysis, Spectral Composition Analysis, Embolization Plan, Spectral Analysis	N/A
Auto MPR			
- Anatomical Region	Brain	N/A	Brain
- Type of Input Data	3D Volumetric CT image	N/A	CT image
- Type of Output Data	The output is intended for PACS display system. - 2D MPR	N/A	The output is intended for PACS display system. - 3D Volumetric - 2D MPR
- Auto reformat for standard viewing of brain images.	Available (OM plane base)	N/A	Available
- Auto Labeling of segmentable brain structures.	N/A	N/A	Available
- Volumetric quantification of brain images (CSF volumes, Intracranial volume, Midline shift)	N/A	N/A	Available

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, IEC60601-1-9, and IEC62366-1.

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. Bench studies were conducted to test Auto MPR output image alignment into a standard anatomical position and assessed the impact of various conditions on Auto MPR image alignment. Results of both these studies demonstrated that Auto MPR met established specifications and performed 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-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, performs in a manner similar to and is intended for the same use as the primary predicate device. The software application, Auto MPR, included in the Vitrea Software Package, VSTP-002A, performs in a manner similar to and is intended for the same use as the reference 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.