Canon Medical Informatics, Inc.
Jay Vaishnav
Director, Regulatory Affairs
5850 Opus Pkwy., Suite 300
Minnetonka, Minnesota 55343

October 29, 2026

Re: K263648
Trade/Device Name: Vitrea Advanced Visualization, Version 7.16
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 1, 2026
Received: October 2, 2026

Dear Jay Vaishnav:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

Please provide the device trade name(s).

Vitrea Advanced Visualization, Version 7.16

Please provide your Indications for Use below.

Vitrea is 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 is not meant for primary image interpretation in mammography.

Please select the types of uses.

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) Summary - K263648

Applicant name	Canon Medical Informatics, Inc.
Applicant address	5850 Opus Parkway, Suite 300, Minnetonka, MN 55343, United States of America
Applicant and correspondent	Jay Vaishnav, PhD, RAC, FRAPS Director, Regulatory Affairs
Phone	952-487-9530
Email	Jay.Vaishnav@mi.medical.canon
Date prepared	September 28, 2026
Device trade name	Vitrea Advanced Visualization Version 7.16
Common name	Vitrea AV 7.16
Classification name	Medical image management and processing system
Regulation number / class	21 CFR 892.2050 / Class II
Subject-device product code / review panel	LLZ / Radiology
Predicate device / regulation	Vitrea Advanced Visualization Version 7.6 (K172855) / 21 CFR 892.2050 (LLZ)
Alternate contact 1	Vincent Swenson Senior Director, Quality and Regulatory Phone: 952-487-9548 Email: Vincent.Swenson@mi.medical.canon
Alternate contact 2	Gargeyi Pavuluri Senior Regulatory Affairs Specialist Phone: 952-487-9875 Email: Gargeyi.Pavuluri@mi.medical.canon
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I. Device Description — 21 CFR 807.92(a)(4)

How the Device Functions

Vitrea Advanced Visualization 7.16 is a medical imaging software system that processes, reviews, analyzes, communicates, and exchanges multi-dimensional digital images. It supports image management, study access, image review and post-processing, measurement and analysis, evidence generation, reporting, and DICOM-based workflow integration.

Scientific Concepts That Form the Basis of the Device

The device applies established medical image-processing and visualization methods to digital image data. User-selected and predefined rule-based functions generate views, measurements, annotations, derived images, and other outputs for review by qualified healthcare professionals.

Proposed Conditions for Use

Vitrea Advanced Visualization is 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 is not limited to a specific disease, condition, or patient population unless otherwise specified in applicable labeling or clinical application documentation.

Physical and Performance Characteristics of the Device

(a)Physical Characteristics

The device is Software as a Medical Device (SaMD) and has no hardware or material components.

(b)Performance Characteristics

Performance was evaluated through software verification and validation, interoperability and DICOM conformance testing, platform compatibility testing, cybersecurity evaluation, risk management, usability evaluation, and bench testing of the Cobb Angle and Cylinder tools. The completed testing demonstrated that the applicable requirements and predefined acceptance criteria were met.

How the Device Interacts with Other Devices and the Patient

The device receives medical image data from imaging devices, PACS, archives, or other configured systems and communicates supported images, derived images, evidence, reports, and other outputs to connected systems using supported interfaces, including DICOM.

II. Intended Use/Indications for Use — 21 CFR 807.92(a)(5)

Vitrea is 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 is not intended for primary image interpretation in mammography.

III. Indications for Use Comparison — 21 CFR 807.92(a)(5)

The subject device and the predicate device have the same indications for use.

IV. Technological Comparison — 21 CFR 807.92(a)(6)

The following is a summary of how the technological characteristics of the subject device compare to the legally marketed predicate device:

Similarities in Technology with Predicate Device

The subject and predicate devices are both medical imaging software systems used to process, review, analyze, communicate, and exchange multi-dimensional medical images. The subject and predicate devices have the same intended use and general technological approach.

Differences in Technology with Predicate Device

Vitrea Advanced Visualization 7.16 includes applicable functionality of the predicate device plus visualization and rendering enhancements, tools, measurement and quantitative analysis enhancements, derived data enhancements, product infrastructure enhancements, workflow and user experience enhancements, interoperability enhancements, cybersecurity, infrastructure, and platform compatibility updates. Unless otherwise noted, the identified differences do not change the intended use, operating principle, or fundamental scientific technology, do not introduce AI/ML functionality and are addressed through applicable design controls, risk management, software verification and validation, interoperability and DICOM conformance testing, cybersecurity documentation, platform compatibility testing, or usability evaluation. The technological differences do not raise new questions of safety or effectiveness and do not adversely affect the safety or effectiveness of the subject device.

Table 1 summarizes the key technological similarities and differences between the subject device and the predicate device.

Table 1. Substantial Equivalence Comparison

Characteristic	Predicate Vitrea Advanced Visualization 7.6 (K172855)	Subject Device Vitrea Advanced Visualization 7.16	Evaluation
Regulation, classification, and product code	21 CFR 892.2050; Class II; LLZ	21 CFR 892.2050; Class II; LLZ	Same.
Intended use and operating principle	Medical imaging software for processing, review, analysis, communication, and exchange of multi-dimensional digital images.	Same intended use, indications for use, and fundamental image-processing approach.	No change to the intended use or fundamental scientific technology.
Image display, processing, measurement, and analysis	Established 2D/3D review, rendering, segmentation, measurement, manipulation, and analysis functions.	Retains predicate functionality and adds workflow, visualization, sculpting, segmentation, tracking, measurement-display, Cylinder-tool, and Cobb Angle updates.	Software verification and validation and bench testing addressed functional performance and measurement accuracy.
Interoperability, outputs, and workflow	DICOM exchange, storage, PACS integration, study access, evidence	Updates DICOM compatibility, external application launch, prior-study access, status notifications, derived-image and evidence	Interoperability, DICOM conformance, software, and workflow testing demonstrated that the updated

	generation, reporting, and STL export.	outputs, additional export formats, and configured routing.	functions met applicable requirements.
Automation	Supports rule-based automated preprocessing and workflow.	Expands rule-based monitoring, workflow optimization, advanced processing, and Automation Platform integration. No AI/ML device functionality is introduced.	Software verification and validation and risk management addressed the modified automated workflows; users retain review of results before clinical use.
Cybersecurity, deployment, and administration	Supports established authentication, administration, monitoring, reporting, and workstation or enterprise deployment.	Updates TLS configuration, certificate visibility, PIV/smart-card sign-in, platform compatibility, and background-processing support.	Cybersecurity evaluation, platform compatibility testing, software verification and validation, and risk management addressed these changes.

V. Performance Data — 21 CFR 807.92(b)

Nonclinical testing included software verification and validation of applicable requirements and risk controls; interoperability and DICOM conformance testing; platform compatibility testing; cybersecurity evaluation; usability evaluation; and bench testing of the Cobb Angle and Cylinder tools. Cobb Angle measurements were compared with predefined reference angles, and Cylinder diameter and height measurements were compared with known phantom dimensions using synthetic and physical phantom datasets that represented multiple imaging modalities, voxel spacings, orientations, and gantry-tilt conditions. The completed testing demonstrated that the software functions performed as specified and that all predefined acceptance criteria were met.

Clinical testing was not required to support the determination of substantial equivalence.

VI. Substantial Equivalence Conclusion

Vitrea Advanced Visualization 7.16 shares the same intended use, indications for use, operating principle, and fundamental scientific technology as Vitrea Advanced Visualization, Version 7.6 (K172855).

The technological differences are limited to software functionality, workflow, interoperability, deployment, cybersecurity, and user-interface updates. The results of software verification and validation, interoperability and DICOM conformance testing, platform compatibility testing, cybersecurity evaluation, risk management, usability evaluation, and Cobb Angle and Cylinder bench testing demonstrate that the subject device performs as intended. These differences do not raise different questions of safety or effectiveness. Therefore, Vitrea Advanced Visualization 7.16 is substantially equivalent to the predicate device.