March 27, 2026

Canon Medical Systems Corporation
Blake Stacy
Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
Tustin, California 92780

Re: K253625
Trade/Device Name: Vantage Fortian/Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: February 26, 2026
Received: February 26, 2026

Dear Blake Stacy:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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

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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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.	K253625

Please provide the device trade name(s).

Vantage Fortian/Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR

Please provide your Indications for Use below.

Vantage Fortian/Orian 1.5T systems are indicated for use as a diagnostic imaging modality that produces cross-sectional transaxial, coronal, sagittal, and oblique images that display anatomic structures of the head or body. Additionally, this system is capable of non-contrast enhanced imaging, such as MRA.
MRI (magnetic resonance imaging) images correspond to the spatial distribution of protons (hydrogen nuclei) that exhibit nuclear magnetic resonance (NMR). The NMR properties of body tissues and fluids are:

•Proton density (PD) (also called hydrogen density)
•Spin-lattice relaxation time (T1)
•Spin-spin relaxation time (T2)
•Flow dynamics
•Chemical Shift

Depending on the region of interest, contrast agents may be used. When interpreted by a trained physician, these images yield information that can be useful in diagnosis.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

1. CLASSIFICATION and DEVICE NAME

Classification Name:	**Magnetic Resonance Diagnostic Device**
Regulation Number:	**90-LNH (Per 21 CFR § 892.1000)**
Trade Proprietary Name:	**Vantage Fortian / Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR**
Model Number:	**MRT-1550**

2. SUBMITTER'S NAME

Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-Shi, Tochigi-ken, Japan 324-8550

3. OFFICIAL CORRESPONDENT

Naofumi Watanabe
Senior Manager, Regulatory Affairs and Vigilance
Canon Medical Systems Corporation

4. CONTACT PERSON, U.S. AGENT and ADDRESS

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5. MANUFACTURING SITE

Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan

6. ESTABLISHMENT REGISTRATION

9614698

7. DATE PREPARED

November 17, 2025

8. DEVICE NAME

Vantage Fortian/Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR

9. TRADE NAME

Vantage Fortian/Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR

10. CLASSIFICATION NAME

Magnetic Resonance Diagnostic Device (MRDD)

11. CLASSIFICATION PANEL

Radiology

12. DEVICE CLASSIFICATION

Class II (per 21 CFR 892.1000, Magnetic Resonance Diagnostic Device)

13. PRODUCT CODE

90-LNH

14. PREDICATE DEVICE

Predicate Device: Vantage Fortian/Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR (K250901)

System	**Predicate Device**
	Vantage Fortian/Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR
Marketed By	Canon Medical Systems USA, Inc.
510(k) Number	K250901
Clearance Date	July 22, 2025

15. REFERENCE DEVICE

Reference Device:

System	Reference Device 1	Reference Device 2
	Vantage Orian 1.5T, MRT-1550, V9.0 with AiCE Reconstruction Processing Unit for MR	Vantage Orian 1.5T, MRT-1550, V6.0 with AiCE Reconstruction Processing Unit for MR
Marketed By	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.
510(k) Number	K240238	K191662
Clearance Date	April 12, 2024	July 23, 2019

16. REASON FOR SUBMISSION

Modification of a cleared device

17. SUBMISSION TYPE

Traditional 510(k) Premarket Notification

18. DEVICE DESCRIPTION

The Vantage Fortian (Model MRT-1550/WK, WM, WO, WQ)/Vantage Orian (Model MRT-1550/U3, U4, U7, U8) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. These Vantage Fortian/Orian models use 1.4 m short and 4.1 tons light weight magnet. They include the Canon Pianissimo Σ and Pianissimo Zen technology (scan noise reduction technology). The design of the gradient coil and the whole-body coil of these Vantage Fortian/Orian models provide the maximum field of view of 55 x 55 x 50 cm and include the standard (STD) gradient system.

The Vantage Fortian (Model MRT-1550/WS, WU)/Vantage Orian (Model MRT-1550/AV, AZ) with modified ASGC is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. These Vantage Fortian/Orian models use 1.4 m short and 4.1 tons light weight magnet. They include the Canon Pianissimo Σ and Pianissimo Zen technology (scan noise reduction technology). The design of the gradient coil and the whole-body coil of these Vantage Fortian/Orian models provide the maximum field of view of 55 x 55 x 50 cm and include the standard (STD) gradient system.

The Vantage Orian (Model MRT-1550/ UC, UD, UG, UH, UK, UL, UO, UP) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Orian models use 1.4 m short and 4.1 tons light weight magnet. They include the Canon Pianissimo and Pianissimo Zen technology (scan noise reduction technology). The design of the gradient coil and the whole-body coil of these Vantage Orian models provide the maximum field of view of 55 x 55 x 50 cm. The MRT-1550/ UC, UD, UG, UH, UK, UL, UO, UP models include the XGO gradient system.

The Vantage Orian (Model MRT-1550/AK, AL, AO, AP, A3, A4, A7, A8, AC, AD, AG, AH (Upgrade only)) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Orian models MRT-1550/A3, A4, A7, A8 use 1.4 m short and 4.1 tons light weight magnet while the Vantage Orian models MRT-1550/AK, AL, AO, AP, AC, AD, AG, AH use 1.4 m short and 3.8 tons light weight magnet. All of the aforementioned models include the Canon Pianissimo and Pianissimo Zen technology (scan noise reduction technology). The design of the gradient coil and the whole-body coil of these Vantage Orian models provide the maximum field of view of 55 x 55 x 50 cm. The Model MRT-1550/AK, AL, AO, AP includes the XGO gradient system. The MRT-1550/A3, A4, A7, A8, AC, AD, AG, AH models include the standard (STD)

gradient system.

The Vantage Orian (Model MRT-1550/AS, AT, AW, AX (Upgrade only)) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Orian uses 1.4 m short and 4.0 tons light weight magnet. It includes the Canon Pianissimo and Pianissimo Zen technology (scan noise reduction technology). The design of the gradient coil and the whole body coil of the Vantage Orian provides the maximum field of view of 55 x 55 x 50 cm and include the standard (STD) gradient system.

This system is based upon the technology and materials of previously marketed Canon Medical Systems MRI systems and is intended to acquire and display cross-sectional transaxial, coronal, sagittal, and oblique images of anatomic structures of the head or body. The Vantage Fortian/Orian MRI System is comparable to the current 1.5T Vantage Fortian/Orian MRI System (K250901), cleared July 22, 2025, with the following modifications.

19. SUMMARY OF CHANGE(S)

This submission is to report the following changes:

Summary of System/Hardware Changes:

- **Addition of systems with modified ASGC**: Modifications have been made to the ASGC, and new model numbers (Fortian: WS, WU; Orian: AV, AZ) for the updated systems have been allocated.

Summary of Software Changes:

- **System addition:** The Software has been updated to add systems with modified ASGC.
- **Expansion of Software Upgrade Package (V10.0):** The Software has been updated so that Software Upgrade Package (V10.0) for Vantage Orian can also support conventional Vantage Orian systems.

20. SAFETY PARAMETERS

Item	Subject Device: Vantage Fortian/Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR	Predicate Device: Vantage Fortian/Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR	Notes
Static field strength	1.5T	1.5T	Same
Operational Modes	Normal and 1st Operating Mode	Normal and 1st Operating Mode	Same
i. Safety parameter display	SAR, dB/dt	SAR, dB/dt	Same
ii. Operating mode access requirements	Allows screen access to 1st level operating mode	Allows screen access to 1st level operating mode	Same
Maximum SAR	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33: 2010+A1:2013+A2:2015)	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33: 2010+A1:2013+A2:2015)	Same

Item	Subject Device: Vantage Fortian/Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR	Predicate Device: Vantage Fortian/Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR	Notes
Maximum dB/dt	1st operating mode specified in IEC 60601-2-33: 2010+A1:2013+A2:2015	1st operating mode specified in IEC 60601-2-33: 2010+A1:2013+A2:2015	Same
Potential emergency condition and means provided for shutdown	Shutdown by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Shutdown by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Same

21. IMAGING PERFORMANCE PARAMETERS

No change from the predicate submission, K250901.

22. INDICATIONS FOR USE

Vantage Fortian/Orian 1.5T systems are indicated for use as a diagnostic imaging modality that produces cross-sectional transaxial, coronal, sagittal, and oblique images that display anatomic structures of the head or body. Additionally, this system is capable of non-contrast enhanced imaging, such as MRA.

MRI (magnetic resonance imaging) images correspond to the spatial distribution of protons (hydrogen nuclei) that exhibit nuclear magnetic resonance (NMR). The NMR properties of body tissues and fluids are:

- Proton density (PD) (also called hydrogen density)
- Spin-lattice relaxation time (T1)
- Spin-spin relaxation time (T2)
- Flow dynamics
- Chemical Shift

Depending on the region of interest, contrast agents may be used. When interpreted by a trained physician, these images yield information that can be useful in diagnosis.

**Note: No change from the predicate submission, K250901*

23. SUMMARY OF DESIGN CONTROL ACTIVITIES

Risk Management activities for this modification are included in this submission. The test methods used are the same as those submitted in the previously cleared submission of the predicate device, Vantage Fortian/Orian 1.5T, MRT-1550, V10.0 with AiCE Reconstruction Processing Unit for MR (K250901). A declaration of conformity with design controls is included in this submission.

24. SAFETY

This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards.

This device is based upon the same technologies, materials and software as the predicate device. Risk activities were conducted in concurrence with established medical device development standards and guidance. Additionally, testing was done in accordance with applicable recognized consensus standards published by the International Electrotechnical Commission (IEC) for medical devices and the National Electrical Manufacturers Association (NEMA):

LIST OF APPLICABLE STANDARDS

- ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
- IEC 60601-1:2005, A1:2012, A2:2020
- IEC 60601-1-2:2014+A1:2020
- IEC 60601-1-6 (2010), Amd.1 (2013), Amd.2 (2020)
- IEC 60601-2-33 (2010), Amd.1 (2013), Amd.2 (2015)
- IEC 60825-1 (2014)
- IEC 62304 (2006), Amd.1 (2015)
- IEC 62366-1 (2020)
- ISO 10993-1 (2018)
- NEMA MS 1:2008 (R2020)
- NEMA MS 2:2008 (R2020)
- NEMA MS 3:2008 (R2020)
- NEMA MS 4 (2010)
- NEMA MS 5 (2018)

25. TESTING

Risk analysis and verification/validation testing conducted through bench testing are included in this submission which demonstrate that the system requirements have been met. No image quality testing was conducted.

Software Documentation for a Basic Documentation Level, per the FDA guidance document, *"Content of Premarket Submissions for Device Software Functions"* issued on June 14, 2023, is included in this submission. This documentation includes justification for the Basic Documentation Level determination as well as testing which demonstrates that the verification and validation requirements have been met.

Cybersecurity documentation, per the FDA cybersecurity premarket guidance document *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"* issued on June 26, 2025, is also included as part of this submission.

26. SUBSTANTIAL EQUIVALENCE

Canon Medical Systems Corporation believes that the changes incorporated into the Vantage Fortian/Orian 1.5T, MRT-1550, V10.0, Magnetic Resonance Imaging (MRI) System with AiCE Reconstruction Processing Unit for MR, are substantially equivalent to the previously cleared predicate device.

27. CONCLUSION

The modifications incorporated into the Vantage Fortian/Orian 1.5T, MRT-1550, V10.0, Magnetic Resonance Imaging (MRI) System with AiCE Reconstruction Processing Unit for MR, do not change the indications for use or the intended use of the device. Based upon the evidence presented, Canon Medical Systems Corporation considers the subject Vantage Fortian / Orian 1.5T device to be as safe, as effective, and with performance that is substantially equivalent to the predicate device.