Canon Medical Systems Corporation
℅ Janine Reyes
Senior Manager, Regulatory Affairs
Canon Medical Systems U.S.A, Inc.
2441 Michelle Drive
Tustin, California 92780

December 1, 2021

Re: K213305
Trade/Device Name: Vantage Fortian 1.5T, MRT-1550, V8.0 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: September 30, 2021
Received: October 4, 2021

Dear Janine Reyes:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K213305

Device Name
Vantage Fortian 1.5T, MRT-1550, V8.0 with AiCE Reconstruction Processing Unit for MR

Indications for Use *(Describe)*
Vantage Fortian 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.

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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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 1.5T, MRT-1550, V8.0 with AiCE Reconstruction Processing Unit for MR**
Model Number:	**MRT-1550**

2. SUBMITTER'S NAME

Canon Medical Systems Corporation
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3. OFFICIAL CORRESPONDENT

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5. **MANUFACTURING SITE**
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6. **ESTABLISHMENT REGISTRATION**
   9614698

7. **DATE PREPARED**
   September 30, 2021

8. **DEVICE NAME**
   Vantage Fortian 1.5T, MRT-1550, V8.0 with AiCE Reconstruction Processing Unit for MR

9. **TRADE NAME**
   Vantage Fortian 1.5T, MRT-1550, V8.0 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 Orian 1.5T, MRT-1550, V7.0 with AiCE Reconstruction Processing Unit for MR (K211633)
    Reference Device: Vantage Orian 1.5T, MRT-1550, V6.0 (K202210) and Vantage Elan 1.5T, MRT-2020, V6.0 (K210164)

	Subject Device	Predicate Device	Reference Device	Reference Device
System	Vantage Fortian 1.5T, MRT-1550, V8.0 with AiCE Reconstruction Processing Unit for MR	Vantage Orian 1.5T, MRT-1550, V7.0 with AiCE Reconstruction Processing Unit for MR	Vantage Orian 1.5T, MRT-1550, V6.0	Vantage Elan 1.5T, MRT-2020, V6.0
Marketed By	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.
510(k) Number	This Submission	K211633	K202210	K210164
Clearance Date		July 22, 2021	September 22, 2020	March 10, 2021

15. REASON FOR SUBMISSION

Modification of a cleared device

16. SUBMISSION TYPE

Traditional 510(k) Premarket Notification

17. DEVICE DESCRIPTION

The Vantage Fortian (Model MRT-1550) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Fortian uses 1.4 m short and 4.1 tons light weight magnet. It includes the Canon Pianissimo™ Σ and Pianissimo Zen technology (scan noise reduction technology). The design of the gradient coil and the whole body coil of the Vantage Fortian provides the maximum field of view of 55 x 55 x 50 cm. The Model MRT-1550/ WK, WM, WO, WQ includes the standard 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 MRI System is comparable to the current 1.5T Vantage Orian MRI System (K211633), cleared July 22, 2021 with the following modifications.

18. SUMMARY OF CHANGE(S)

This submission is to report the following changes:

Summary of Hardware Changes:

- **Gantry color change.**
- **RF System:**
  - Number of transmission channel was changed from 2ch to 1ch.
  - Maximum power of RF amplifier was changed from 30kW(2ch) to 24kW(1ch).
- **Maximum gradient amplitude (per axis) [mT/m], maximum slew rate [mT/m/ms], and rise time [ms] changes:**

System	Subject Device	Predicate Device K211633	Reference Device K202210
	Vantage Fortian 1.5T, MRT-1550, V8.0 with AiCE Reconstruction Processing Unit for MR	Vantage Orian 1.5T, MRT-1550, V7.0 with AiCE Reconstruction Processing Unit for MR	Vantage Orian 1.5T, MRT-1550, V6.0
Maximum Gradient Amplitude	35 [mT/m]	45 [mT/m]	34 [mT/m]
Rise Time	0.226 [ms]	0.225 [ms]	0.220 [ms]
Maximum Slew Rate	155 [mT/m/ms]	200 [mT/m/ms]	155 [mT/m/ms]

- **New Gradient coil:** Changed to another vender.
- **WB coil changed:** Number of rung changed.

- **Canon Pianissimo™ Σ:** Pianissimo Σ technology dramatically reduces the level of acoustic gradient noise, thus substantially enhancing patient comfort, especially during scanning with fast sequences (K210164).
- **Water cooling system:** Branch of cooling water by cooling cabinet to RFA, GPS, Refrigerator Compressor. For Gradient coil, cooling water is supplied by Heat Exchanger. Eco cooling system is not available.

Summary of Software Changes:

- **Artifacts Suppression Techniques:**
    - **mART EXP:** mART EXP is 3D method to resolve in-plane and through-plane distortion artifact induced by susceptibility. Each slice is 3D phase-encoded to resolve distortion in slice dimension. In addition, VAT method is combined to resolve in-plane distortion. In the reconstruction, the data of each slice which is encoded in the slice direction is combined and corrected, and finally the images are registered as 2D multi-slice images like normal FSE2D. In addition, this application can be used in combination with Compressed SPEEDER application to reduce scan time.
    - **RDC DWI:** RDC DWI is the method to reduce distortion in phase encoding direction for SEEPI2D sequence. The direction of distortion described above can be reversed by reversing the phase encoding polarity. Hence, the pair of the data that have reversed phase encoding polarity each other is acquired, and then the distortion in reconstructed images can be reduced by estimating displacements between them. In addition, this application can be used in combination with SPEEDER or Exsper.
- **pCASL (pseudo-continuous ASL):** pCASL is one of the arterial spin labeling (ASL) techniques which can provide perfusion-weighted images without contrast media by subtracting the tag image from the control image. Unlike ASTAR based on pulsed ASL (PASL) technique which asymmetrically applies single tag and control IR pulse on the upper and lower sides of the imaging slab, pCASL uses a train of very short RF pulses with thinner thickness than ASTAR for both tag and control applied upstream of the inflow artery with respect to the imaging slab.
- **Iterative Motion Correction (IMC):** IMC reduces motion artifact by correcting k-space data based on detecting the amount of motion during scan.
- **SureVOI Liver:** Sure VOI Liver automatically detects liver area and plan scan position for shimming scan, map scan, axial scan, coronal scan, probe scan for Real-time Motion Correction (RMC), and VisualPrep scan. The positions of the detected planes can be adjusted using functions provided in the Scan Plan window.
- **LiverLine+:** Machine Learning based detection technology for liver plane. Using 2D images as the input, two kinds of MRCP scan plan (MRCP 3D and MRCP 2D) are automatically detected and set for the scan positioning ROIs. The orientations and positions of the detected basic planes can be adjusted using functions provided in the Scan Plan window.
- **ProstateLine+:** Machine Learning based detection technology for prostate plane. Using 3D images as the input, five planes (axial, coronal, sagittal, oblique axial, and oblique coronal) of

the prostate are automatically detected and set for the scan positioning ROIs. The orientations and positions of the detected planes can be adjusted using functions provided in the Scan Plan window.

- **W-SpineLine+:** Machine Learning based detection technology for spine plane. Using 3D images of multiple stations covered whole spine region as the input, three planes (sagittal, coronal, and spinal disc planes) conforming to the curvature of the spine are automatically detected and set for the scan positioning ROIs. The orientations and positions of the detected basic planes can be adjusted using functions provided in the Scan Plan window. It is also possible to label to detected spinal discs and can be adjusted using functions provided in the W-SpineLine+ window.
- **Exsper Sequence Expansion**: Exsper is available in FSE2D in addition to SE-EPI(DWI)

Summary of Accessory Changes:

- **Ceiling Camera:** The ceiling camera, in combination with the intelligent monitor, provides the operator with real-time coil positioning and patient centering assistance.
- **Apps for Tablet UX**: The application, installed on a tablet, allows the operator to prepare for the next patient study and monitor examination progress. This option allows to install an application for the Tablet UX to tablet from Host PC of the MRI system via web browser on a tablet.

19. SAFETY PARAMETERS

Item	Subject Device: Vantage Fortian 1.5T, MRT-1550, V8.0	Predicate Device: Vantage Orian 1.5T, MRT-1550, V7.0 K211633	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
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

20. IMAGING PERFORMANCE PARAMETERS

No change from the previous predicate submission, K211633.

21. INDICATIONS FOR USE

Vantage Fortian 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.

22. SUMMARY OF DESIGN CONTROL ACTIVITIES

Risk Management activities for new software functionalities and pulse sequences 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 Orian 1.5T, MRT-1550, V7.0 (K211633). A declaration of conformity with design controls is included in this submission.

23. 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 ES60601-1:2005 / (R)2012 and A1:2012
- IEC60601-1-2 (2014)
- IEC60601-1-6 (2010), Amd.1 (2013)
- IEC60601-2-33 (2010), Amd.1 (2013), Amd.2 (2015)
- IEC60825-1 (2007, 2014)
- IEC62304 (2006), Amd.1 (2015)
- IEC62366-1 (2020)
- NEMA MS 1 (2008)
- NEMA MS 2 (2008)
- NEMA MS 3 (2008)
- NEMA MS 4 (2010)
- NEMA MS 5 (2018)

24. 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. Additionally, image quality testing was completed which demonstrated that the subject device meets predetermined acceptance criteria.

SureVOI Liver, LiverLine+, ProstateLine+, and W-SpineLine+ were evaluated using volunteer images. It was confirmed that these features worked as intended, the images were of diagnostic quality, and the test results met predetermined acceptance criteria.

Exsper in FSE2D was evaluated utilizing phantom images. It was confirmed that Exsper reduces artifacts caused by unfolding errors, compared to traditional SPEEDER.

MR image quality metrics were performed, utilizing phantom images, to assess mART EXP. Testing verified mART EXP can reduce distortion artifacts in the readout direction like mART+ and can also reduce distortion artifacts in the slice direction more than mART+.

IMC (Iterative Motion Correction) was evaluated using volunteer images. Testing confirmed that IMC is effective in reducing motion artifacts.

RDC DWI was evaluated utilizing phantom images. It was confirmed that the distortion in phase encoding direction was reduced by RDC DWI as compared to conventional images without RDC DWI in SEEPI2D sequence.

pCASL (pseudo-continuous ASL) was evaluated utilizing phantom images. Testing confirmed CBF values via pCASL met predetermined acceptance criteria.

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 included as part of this submission.

25. SUBSTANTIAL EQUIVALENCE

Canon Medical Systems Corporation believes that the Vantage Fortian 1.5T, MRT−1550, V8.0 Magnetic Resonance Imaging (MRI) System is substantially equivalent to the previously cleared predicate device, Vantage Orian 1.5T, MRT-1550, V7.0, referenced in this submission.

Canon Medical Systems Corporation believes that the changes incorporated into the Vantage Fortian 1.5T, MRT-1550, V8.0 are substantially equivalent to the previously cleared predicate device.

26. CONCLUSION

The modifications incorporated into the Vantage Fortian 1.5T, MRT-1550, V8.0 do not change the indications for use or the intended use of the device. Based on the indications for use, technological characteristics, and safety and performance testing, the subject device meets the requirements that are considered adequate for its intended use and is substantially equivalent in design, principles of operation and indications for use to the predicate device.