Canon Medical Systems Corporation
% Ms. Janine F. Reyes
Manager, Regulatory Affairs
Canon Medical Systems USA, INC.
2441 Michelle Drive
TUSTIN CA 92780

July 22, 2021

Re: K211633
Trade/Device Name: Vantage Orian 1.5T, MRT-1550, V7.0 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: May 25, 2021
Received: May 27, 2021

Dear Ms. 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)*

K211633

Device Name

Vantage Orian 1.5T, MRT-1550, V7.0 with AiCE Reconstruction Processing Unit for MR

Indications for Use *(Describe)*

Vantage 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.

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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CANON MEDICAL SYSTEMS USA, INC.

Made For life

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 Orian 1.5T, MRT-1550, V7.0 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
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4. CONTACT PERSON, U.S. AGENT and ADDRESS

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5. **MANUFACTURING SITE**
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   1385 Shimoishigami
   Otawara-shi, Tochigi 324-8550, Japan

6. **ESTABLISHMENT REGISTRATION**
   9614698

7. **DATE PREPARED**
   May 25, 2021

8. **DEVICE NAME**
   Vantage Orian 1.5T, MRT-1550, V7.0 with AiCE Reconstruction Processing Unit for MR

9. **TRADE NAME**
   Vantage Orian 1.5T, MRT-1550, V7.0 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 (system): Vantage Orian 1.5T, MRT-1550, V6.0 (K202210)
    Reference Devices: Vantage Orian 1.5T, MRT-1550, V7.0 with AiCE Reconstruction Processing Unit for MR (K203053) and Vantage Orian 1.5T, MRT-1550, V6.0 with AiCE Reconstruction Processing Unit for MR (K202767).

	Subject Device	Predicate Device	Reference Device	Reference Device
System	Vantage Orian 1.5T, MRT-1550, V7.0 with AiCE Reconstruction Processing Unit for MR	Vantage Orian 1.5T, MRT-1550, V6.0	Vantage Orian 1.5T, MRT-1550, V7.0 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.	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.
510(k) Number	This Submission	K202210	K203053	K202767
Clearance Date		September 22, 2020	December 2, 2020	January 15, 2021

15. REASON FOR SUBMISSION

Modification of a cleared device

16. SUBMISSION TYPE

Traditional 510(k) Premarket Notification

17. DEVICE DESCRIPTION

The Vantage Orian (Model MRT-1550) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Orian uses 1.4 m short and 4.1 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. The Model MRT-1550/ UC, UD, UG, UH, UK, UL, UO, UP includes the XGO 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 Orian MRI System is comparable to the current 1.5T Vantage Orian MRI System (K202210), cleared September 22, 2020 with the following modifications.

18. SUMMARY OF CHANGE(S)

This submission is to report the following changes:

Summary of Hardware Changes: (subject modification)

- **Gradient amplifier for XGO is applied** (K203053). Maximum gradient amplitude (per axis) [mT/m], maximum slew rate [mT/m/ms], and rise time [ms] changes:
  - **Increased Gradient Strength:** increased gradient strength from 34 [mT/m] to 45 [mT/m].
  - **Maximum Slew Rate Change:** maximum slew rate of gradient field was changed from 155 [mT/m/ms] to 200 [mT/m/ms].
  - **Rise Time Change:** rise time changed from 0.220 ms to 0.225 ms.
- **Gradient coil minor change:** minor change to Zch wire position.

Summary of Software Changes:

- **FASE 3D/FFE3D:**
  - **Compressed SPEEDER (Compressed Sensing 3D):** This application allows acceleration factors for shorter scan times or higher resolution in FASE3D and FFE3D in addition to FSE2D, imaging based upon the principle of compressed sending in combination with parallel imaging (K203053).
- **FE 3D:**
  - **Fat Fraction Quantification:** Data is acquired with several different TE and provides PDFF image, R2* image, water image, fat image, in phase image and out of phase image (total 6 kind of images). Proton Density Fat Fraction data and R2* data is supporting fat content ratio (K203053).

- **EPI:**
  - **Exsper (Expanded SPEEDER)**: This application allows reducing scan time for diffusion imaging, Exsper technique scans center of k-space data but surrounding area data is undersampled. It finds coefficient from the data of center k-space and synthesizes the undersampled data by using surrounding data and the coefficient (K203053).
  - **Exsper (Expanded SPEEDER):** The number of maximum acceleration factor changes to 6 (subject modification).
- **FFE 3D:**
  - **Fast 3D for SSFP:** This application allows Fast 3D mode in SSFP 3D sequences, which helps to reduce the scan time by about 50% (K203053).
- **3D Time-of-Flight (TOF):**
  - **Fast 3D for TOF:** This application allows reducing the scan time while maintaining image quality by up to half for TOF images by adjusting data acquisition ratio (K203053).
- **Short T2* map (multi echo-UTE):** UTE imaging is available for acquisition of different TE data for T2* mapping of tissues with short T2* (K203053).
- **Advanced DWI-Diffusion time:** Various diffusion times are available (K203053).
- **AiCE (Advanced Intelligent Clear-IQ Engine):**
  - **AiCE anatomical region expansion:** Head (brain), MSK (shoulder, elbow, wrist/hand, hip, knee, foot/ankle), Spine (cervical, thoracic, lumbar), Pelvis (soft tissue pelvis, female, prostate), Abdomen (liver, renal, pancreas), Breast, Cardiac (K202767).
  - **AiCE noise estimation improvement:** By taking into consideration g-factor, noise can be removed from the part where g-factor was considered (K203053).
- **RX/TX Correction plus:** The intensity nonuniformity due to the sensitivity distribution of the coil during transmission and reception can be corrected. The RX/TX Correction plus function can be used for the chest, extremities, and joints, for which the RX/TX Correction function cannot be used (subject modification).
- **Double Coverage Interleave:** The planned slices are divided into coverages at intervals of N-1 slices, where N is the number of coverages, and then the coverages are excited sequentially. In addition, Interleave acquisition is applied in each coverage (subject modification).

Summary of Accessory Changes:

- **RF Coils:** The following RF coils, previously cleared by the OEM (Quality Electrodynamics, LLC) via 510(k) premarket notification K200477, are added:
  - **Shape Coil, MJAB-207A (subject modification)**
  - **Shape Coil W, MJAB-217A (subject modification)**
- **Patient Pads:** surface material change.
- **Respiratory Gating System Belt:** material change.

Summary of labeling Change:

- **M-Power:** *"M-Power"* marketing name is removed (subject modification).

19. SAFETY PARAMETERS

Item	Subject Device: Vantage Orian 1.5T, MRT-1550, V7.0	Predicate Device: Vantage Orian 1.5T, MRT-1550, V6.0	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, K202210.

21. INDICATIONS FOR USE

Vantage 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.

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, V6.0 (K202210). 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)
- IEC62304 (2006), Amd.1 (2015)
- IEC62366 (2007), Amd.1 (2014)
- 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.

MR image quality metrics were performed, utilizing phantom images, to assess Rx/Tx Correction Plus with regards to image homogeneity. It was concluded that Rx/Tx Correction Plus increases the homogeneity of the image compared to the image without intensity correction.

MR image quality metrics were performed, utilizing phantom images, to assess Exsper (expanded SPEEDER) maximum acceleration factor of up to six with regards to image distortion, homogeneity, low contrast and SNR. It was confirmed that the distortion due to magnetic field inhomogeneity was reduced by increasing the Exsper acceleration factor.

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 Orian 1.5T, MRT−1550, V7.0 Magnetic Resonance Imaging (MRI) System is substantially equivalent to the previously cleared predicate device, Vantage Orian 1.5T, MRT-1550, V6.0, referenced in this submission.

Canon Medical Systems Corporation believes that the changes incorporated into the Vantage Orian 1.5T, MRT-1550, V7.0 are substantially equivalent to the previously cleared predicate device.

26. CONCLUSION

The modifications incorporated into the Vantage Orian 1.5T, MRT-1550, V7.0 do not change the indications for use or the intended use of the device. Based upon bench testing, volunteer clinical imaging, successful completion of software validation and application of risk management and design controls, it is concluded that the subject device is safe and effective for its intended use.