April 12, 2024

Canon Medical Systems Corporation
% Orlando Tadeo
Senior Manager, Regulatory Affairs
Canon Medical Systems, USA
2441 Michelle Drive
Tustin, California 92780

Re: K240238
Trade/Device Name: Vantage Fortian/Orian 1.5T, MRT-1550, V9.0 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: January 29, 2024
Received: January 29, 2024

Dear Orlando 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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240238

Device Name

Vantage Fortian/Orian 1.5T, MRT-1550, V9.0 with AiCE Reconstruction Processing Unit for MR

Indications for Use *(Describe)*

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.

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.

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 Fortian / Orian 1.5T, MRT-1550, V9.0 with AiCE Reconstruction Processing Unit for MR**
Model Number:	**MRT-1550**

2. SUBMITTER'S NAME

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

3. OFFICIAL CORRESPONDENT

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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

January 29, 2024

8. DEVICE NAME

Vantage Fortian/Orian 1.5T, MRT-1550, V9.0 with AiCE Reconstruction Processing Unit for MR

9. TRADE NAME

Vantage Fortian/Orian 1.5T, MRT-1550, V9.0 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, V8.0 with AiCE Reconstruction Processing Unit for MR (K222968)

Reference Device: Vantage Galan 3T, MRT-3020, V9.0 with AiCE Reconstruction Processing Unit for MR (K230355)

System	Predicate Device	Reference Device
	Vantage Fortian/Orian 1.5T, MRT-1550, V8.0 with AiCE Reconstruction Processing Unit for MR	Vantage Galan 3T, MRT-1550, V9.0 with AiCE Reconstruction Processing Unit for MR
Marketed By	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.
510(k) Number	K222968	K230355
Clearance Date	October 25, 2022	August 30, 2023

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/ WK, WM, WO, WQ)/Vantage Orian (Model MRT-1550/ A3, A4, A7, A8) 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 gradient system.

The Vantage Orian (Model MRT-1550/ UC, UD, UG, UH, UK, UL, UO, UP, AK, AL, AO, AP, Upgrade only: A3, A4, A7, A8, AC, AD, AG, AH) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Orian models MRT-1550/ UC, UD, UG, UH, UK, UL, UO, UP, Upgrade only: 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, Upgrade only: 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/ UC, UD, UG, UH, UK, UL, UO, UP, AK, AL, AO, AP includes the XGO gradient system. The Model MRT-1550/ A3, A4, A7, A8, AC, AD, AG, AH include 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/Orian MRI System is comparable to the current 1.5T Vantage Fortian/Orian MRI System (K222968), cleared October 25, 2022, with the following modifications.

18. SUMMARY OF CHANGE(S)

This submission is to report the following changes:

Summary of Software Changes:

- **Exsper:** Exsper has been updated to support 3D encoding sequences. FASE2D/3D, FE3D, FFE2D/3D, and SSFP2D/3D have been also supported.
- **Slice shimming:** When performing the multi-slice image acquisition, parameters for magnetic field homogeneity are corrected per slice.
- **Iterative Motion Correction (IMC):** IMC has been updated to utilize Deep Learning based methods in addition to traditional model-based methods.
- **Free Breathing Dynamic:** Free Breathing Dynamic is contrast enhanced dynamic imaging technique. Utilizing Deep Learning reconstruction, Free Breathing Dynamic enables a single continuous scan to aid patients who have difficulty holding their breath.
- **UTE imaging:** UTE imaging has been updated to support CG-Recon to reduce the scan time while maintaining resolution and SNR.
- **Precise IQ Engine (PIQE):** PIQE is Deep Learning based technique that generates higher in-plane matrix images from low matrix images while mitigating the ringing artifact. PIQE is targeted for brain and knee regions.
- **Auto Protocol Brain Application:** Auto Protocol Brain Application allows to automatically proceed with examination according to a pre-defined scenario.

- **Auto Consult Brain Package:** Auto Consult performs the examinations for brain region all the way from patient setting down to the scan and check.
- **NeuroLine+:** NeuroLine+ has been updated to utilize Machine Learning based method.
- **Auto Scan Assist:** Auto Scan Assist takes away the variability and helps operators improve workflow with automatic slice alignment, standardizing workflow with automatic positioning. Planning of re-scan which is based on the result of image analysis are also available.
- **Ringing correction:** Ringing Correction detects areas in the image that contain truncation artifacts and then reduces or eliminates the artifacts by applying minute subpixel shifting to the pixels in those areas of the image. Ringing correction is targeted for head imaging.

Summary of Accessory Changes:

- **Tablet UX:** Tablet UX has been updated so that display movie from patient camera can be displayed on tablet, voice communication with a patient to be available and scan control to be possible.
- **10GbE High-speed reconstruction kit:** This kit increases the communication speed of the AiCE reconstruction processing unit for MR.
- **Ceiling camera:** Position calculation method for some body regions have been updated.

19. SAFETY PARAMETERS

Item	Subject Device: Vantage Fortian/Orian 1.5T, MRT-1550, V9.0 with AiCE Reconstruction Processing Unit for MR	Predicate Device: Vantage Fortian/Orian 1.5T, MRT-1550, V8.0 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
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, K222968.

21. 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.

22. 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, V8.0 with AiCE Reconstruction Processing Unit for MR (K222968). 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, C1:2009/(R)2012 and A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
- IEC60601-1:2005, A1:2012, A2:2020
- IEC60601-1-2:2014+A1:2020
- IEC60601-1-6 (2010), Amd.1 (2013), Amd.2 (2020)
- IEC60601-2-33 (2010), Amd.1 (2013), Amd.2 (2015)
- IEC60825-1 (2007, 2014)
- IEC62304 (2006), Amd.1 (2015)
- IEC62366-1 (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 (2010, 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.

Exsper 3D was evaluated utilizing phantom images. Testing confirmed that Exsper 3D reduced artifacts caused by unfolding error compared to conventional SPEEDER.

Slice Shim was evaluated using clinical images. Testing confirmed that images with the Slice Shim were equal to or better than those with the Standard Shim especially for off-center slices.

UTE (Ultra Short TE) CG Recon was evaluated utilizing both phantom and clinical images. Testing confirmed CG recon performs better at maintaining both image resolution and image SNR as compared to conventional grid recon when scan time is reduced.

Ringing Correction was evaluated utilizing both phantom and clinical images. Testing confirmed Ringing Correction reduced ringing and met predetermined acceptance criteria.

Auto Scan Assist was evaluated utilizing clinical images. Testing confirmed the operation of slice positioning utilizing Auto Scan Assist applications NeuroLine+, ^{SURE}VOI Liver, LiverLine+, ProstateLine+, and W-SpineLine+ resulted in less time and less steps as compared to slice positioning without Auto Scan Assist.

Ceiling Camera patient orientation and patient anatomy position detection method was evaluated using clinical images. Testing confirmed the percentage of successful patient orientation detection and cases requiring no correction for successful patient anatomy position detection met predetermined acceptance criteria. Additionally, testing confirmed the ceiling camera resulted in less or comparable patient setting time compared to conventional manual patient setting, regardless of the operator.

PIQE (Precise IQ Engine) for MR underwent performance (bench testing) using ACR phantom images. Using metrics of SNR and signal intensity profiles for ringing and sharpness, testing confirmed PIQE generates higher in-plane matrix from lower matrix image and PIQE contributes to ringing artifact reduction and increase of sharpness. The bench testing also included evaluation in typical clinical images of brain and knee, the metrics of Edge Slope Width (to evaluate image sharpness), Ringing Variable Mean (to evaluate ringing artifacts), Signal-to-Noise ratio, and Contrast Change Ratio. Comparing images with PIQE at various scaling factors to standard clinical techniques such as zero-padding interpolation and GA filter, confirmed that PIQE generates images with sharper edges while mitigating the smoothing and ringing effects and maintaining similar or better contrast and SNR.

Additionally, a randomized, blinded clinical image review study was conducted with 6 USA board certified radiologists (3 per anatomy). Using the conventional method (i.e., matrix expansion with Fine Reconstruction and processing with GA Filter) as a reference, the images reconstructed with either the conventional method or the new method PIQE were randomized, blinded to the reviewers, and scored by the 3 reviewers per anatomy in various clinically-relevant categories (including ringing, sharpness, SNR, overall IQ, and feature conspicuity) using a modified 5-point Likert scale, where 3 or above is considered clinically acceptable. A total of 36 unique subjects, from two sites in France, were scanned in

brain or knee to provide the test data sets separately from the training data sets using Vantage Orian or Fortian 1.5T and anatomy-appropriate coils, comprising a total of 252 scans (neuro and knee), in multiple orientations (axial, sagittal and coronal), and multiple contrast weightings (T1-/T2-/PD-weighted with/without Fat saturation) within the FSE2D family of pulse sequences. The resulting reconstructions (conventional and new) were all scored at, or above, clinically acceptable by three board-certified Radiologists per anatomy. The reviewers exhibited a strong agreement at the "good" and "very good" level for all IQ metrics such as SNR, image sharpness, image ringing, overall IQ and feature conspicuity. In conclusion, Testing confirmed (a) PIQE generates higher spatial in-plane resolution images from lower resolution images (with the ability to triple the matrix dimensions in both in-plane directions, i.e. a factor of 9x), (b) PIQE contributes to ringing artifact reduction, denoising and increased sharpness, (c) PIQE is able to accelerate scanning by reducing the acquisition matrix only, while maintaining clinical matrix size and image quality, (d) PIQE benefits can be obtained on regular clinical protocols without requiring acquisition parameter adjustment.

NeuroLine+ underwent performance (bench) testing using clinical images. Testing of NeuroLine+ was conducted with an independent group of patients, newly collected, and entirely separate from the training group. The data, comprising 15 clinical cases (4 male, 11 female, height = 166±7, weight = 73±17, BMI = 27±6, Age = 52±21, national identities include France), were acquired with the typical localizer imaging condition of Fast Field Echo 3D sequence (TR/TE = 3.7/1.3 [ms], Matrix = 128 x 128 x 128, Spatial resolution = 2.5 [mm] isotropic) on the Vantage Orian 1.5T System. The acceptance criterion was a successful scan alignment (i.e., offset and angle within acceptable error defined as typical inter-rater variability) greater than 80% of the time. To assess the accuracy of the auto-detected angle or center position of the target planes, the angle and position of the target planes were manually annotated by two experienced ARRT licensed MR technologists. For the angular error, NeuroLine+ met the acceptance criteria being similar or better as compared to the conventional method. For the auto-positioning, NeuroLine+ yielded 97.5% success which met the acceptance criteria. The results support the conclusion that NeuroLine+ is a clinically acceptable option for the slice-alignment procedure in head examination.

Iterative Motion Correction (IMC) underwent performance (bench testing) using clinical datasets (12) without subject motion and with mathematically simulated motion added. Using the metrics of peak SNR and structural similarity (SSIM), testing demonstrated that IMC is effective in reducing motion artifacts and met predetermined acceptance criteria.

With scanning protocols typically employed clinically for brain and cervical spine, 18 volunteers were imaged at 1.5T in the head and neck coil with various orientations and weightings using the FSE 2D family of sequences. Two acquisitions of each image type and orientation were acquired, one with subject motionless, the other with subject moving as instructed. From the two acquisitions, three reconstructions were performed. The motion free acquisition was reconstructed using typical clinical routine, and the image acquired during the subject motion was reconstructed in two ways: once without IMC applied and again with IMC applied. In total, there were 300 image volumes (100 per group). The image review using the randomized and blinded 300 image volumes was performed. Three US board certified radiologists, specializing in neuro imaging, read and scored the images in various clinically relevant categories (such as SNR, tissue contrast, image sharpness, and diagnostic confidence) based on a pre-determined 5-point modified Likert scale, where a value of 3 or greater was considered clinically acceptable. Testing confirmed the IMC technique performs as expected, significantly reducing

motion artifacts, and improving overall image quality metrics as evaluated via SNR, tissue contrast, image sharpness, and diagnostic confidence. IMC corrected images are the same as, or better than, images without IMC applied.

Another clinical image review was performed by the three US board certified radiologists using an additional 49 image volumes in brain or cervical spine acquired, at 1.5T, from 15 typical clinical patients with pathology and motion. This study further confirmed the diagnostic information in IMC images was the same or better than those without IMC applied. All testing data were acquired separately and independently from the training data after the machine learning training was completed.

Free Breathing Dynamic DLR. The automatic arterial phase detection feature of Free Breathing Dynamic DLR underwent performance (bench) testing using clinical images from patients receiving clinically indicated contrast. Firstly, testing of the arterial phase detection was conducted with 11 clinical cases (5 male, 5 female, 1 unknown, age = 61±11, height = 173±13 years, weight = 78±15 kg, BMI = 26±4, national identities include France and USA), and yielded 90.9% success (i.e., the automatically proposed phases included the gold standard phase as manually selected by experienced radiologists) which met the acceptance criteria (greater than or equal to 80%). Additionally, a clinical image review was conducted with 2 US board certified radiologists who read and scored a total of 29 (14 male, 14 female, 1 unknown, age = 63±12, national identities include United States, France and Japan) contrast enhanced Free Breathing Dynamic liver studies (50 slices per study, repeated for 23 dynamic phases) acquired using either Galan 3T or Orian 1.5T scanner. Based on a modified 5-point Likert scale in categories of diagnostic importance, a score of 3 or higher was considered clinically acceptable. The average of visual scores for overall SNR, overall IQ, feature conspicuity and diagnostic confidence met the acceptance criteria. All testing data were acquired separately and independently from the training data after the machine learning training was completed. The results support the conclusion that Free Breathing Dynamic is a clinically acceptable option for the acquisition of free-breathing contrast enhanced dynamic liver exams providing acceptable diagnostic confidence.

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 September 27, 2023, is also included as part of this submission.

25. SUBSTANTIAL EQUIVALENCE

Canon Medical Systems Corporation believes that the Vantage Fortian/Orian 1.5T, MRT-1550, V9.0, Magnetic Resonance Imaging (MRI) System with AiCE Reconstruction Processing Unit for MR, is substantially equivalent to the previously cleared predicate device referenced in this submission.

Canon Medical Systems Corporation believes that the changes incorporated into the Vantage Fortian/Orian 1.5T, MRT-1550, V9.0, Magnetic Resonance Imaging (MRI) System with AiCE Reconstruction Processing Unit for MR, are substantially equivalent to the previously cleared predicate device.

26. CONCLUSION

The modifications incorporated into the Vantage Fortian/Orian 1.5T, MRT-1550, V9.0, 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 bench testing, 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.