Canon Medical Systems Corporation
% Mr. Paul Biggins, Jr.
Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
TUSTIN CA 92780

January 15, 2021

Re: K202767
Trade/Device Name: Vantage Orian 1.5T, MRT-1550, V6.0 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: December 10, 2020
Received: December 11, 2020

Dear Mr. Biggins:

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)*
K2O2767

Device Name
Vantage Orian 1.5T, MRT-1550, V6.0 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 Orian 1.5T, MRT-1550, V6.0 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**
   September 14, 2020

8. **DEVICE NAME**
   Vantage Oran 1.5T, MRT-1550, V6.0 with AiCE Reconstruction Processing Unit for MR

9. **TRADE NAME**
   Vantage Oran 1.5T, MRT-1550, V6.0 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 (AiCE): Vantage Orian 1.5T, MRT-1550, V6.0 with AiCE Reconstruction Processing Unit for MR (K193097)
    Reference Device (system): Vantage Orian 1.5T, MRT-1550, V6.0 (K193021)

TABLE No. 1: Primary Predicate Device

System	Subject Device	Predicate Device
	Vantage Orian 1.5T, MRT-1550, V6.0	**Predicate Device (AiCE):** Vantage Orian 1.5T, MRT-1550, V6.0
Marketed By	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.
510(k) Number	This Submission	K193097
Clearance Date		July 14, 2020

15. **REASON FOR SUBMISSION**
    Addition of anatomical regions with no changes to the cleared software and hardware.

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 3.8 tons light weight magnet. It includes the Pianissimo™ technology (scan noise reduction technology). The design of the gradient coil and the WB coil of the Vantage Orian 1.5T provides the maximum field of view of 55 x 55 x 50 cm. The Model MRT-1550/AC, AD, AG, AH includes the standard gradient system and Model MRT-1550/AK, AL, AO, AP includes the XGO gradient system. The **AiCE Reconstruction Processing Unit for MR** is included with this system for the processing of images for various anatomical regions.

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 (K193021), cleared June 3rd, 2020.

18. SUMMARY OF CHANGE(S)

Addition of the following anatomical regions;

Subject Device		Predicate Device (K193097)
Anatomical Region	Sub-categories	
Head	Brain	Yes
MSK	Knee	Yes
Spine	Cervical, Lumbar, Thoracic	New
MSK	Shoulder, Hip, Elbow, Wrist/Hand, Foot/Ankle	New
Pelvis	Female, Pelvis (soft tissue), Prostate	New
Abdomen	Liver, Renal, Pancreas	New
Breast	No Sub-category	New
Cardiac	No Sub-category	New

19. SAFETY PARAMETERS (unchanged)

Item	**Subject Device: Vantage Orian 1.5T, MRT-1550, V6.0**	**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

Item	Subject Device: Vantage Orian 1.5T, MRT-1550, V6.0	Predicate Device: Vantage Orian 1.5T, MRT-1550, V6.0	Notes
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, K193021.

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

No change from the previous predicate submission, K193021. 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 submission is a modification that expands the clinical regions for the AiCE Deep Learning Reconstruction. There are no changes to the software and hardware from the previous Pre-Market Notification 510(k) K193021.

24. TESTING

AiCE deep learning reconstruction underwent performance (bench testing) using a model observer study to determine that image low contrast detectability was maintained or improved, accompanied with other bench testing of SNR and contrast performance. Additionally, a human observer study was conducted with 6 board certified radiologists and 55 studies that demonstrated a statistical preference of AiCE when compared to other performance filters. The results of the testing demonstrated that AiCE performed either at the same level or above the performance of the commercially available predicate device.

25. SUBSTANTIAL EQUIVALENCE

Canon Medical Systems Corporation believes that the Vantage Orian 1.5T, MRT−1550, V6.0, Magnetic Resonance Imaging (MRI) System with AiCE Reconstruction Processing Unit for MR is substantially equivalent to the previously cleared predicate device, Vantage Orian 1.5T, MRT-1550, V6.0, As there is no change to the hardware and software of the predicate device. Additionally, the testing conducted demonstrates that the device performance is equivalent to the predicate device for the anatomical regions that are stated above.

26. CONCLUSION

The Vantage Orian 1.5T, MRT-1550, V6.0 with AiCE Reconstruction Processing Unit for MR does not have any change for the indications for use or the intended use of the device. Bench testing and volunteer clinical imaging additionally conducted does not change the conclusion that the subject device is safe and effective for its intended use.