Re: K193097
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: June 3, 2020
Received: June 5, 2020

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
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/comparison-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.


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
Indications for Use

Device Name
Vantage Orian 1.5T, MRT-1550, V6.0 with AiCE Reconstruction Processing Unit for MR

510(k) Number (if known)
K193097

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASstaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
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

<table>
<thead>
<tr>
<th>Classification Name:</th>
<th>Magnetic Resonance Diagnostic Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Number:</td>
<td>90-LNH (Per 21 CFR § 892.1000)</td>
</tr>
<tr>
<td>Trade Proprietary Name:</td>
<td>Vantage Orian 1.5T, MRT-1550, V6.0 with AiCE Reconstruction Processing Unit for MR</td>
</tr>
<tr>
<td>Model Number:</td>
<td>MRT-1550</td>
</tr>
</tbody>
</table>

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

Contact Person
Janine F. Reyes
Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 669-7853
Fax: (714) 730-1310
E-mail: jfreyes@us.medical.canon

Official Correspondent/U.S. Agent
Paul Biggins
Senior Director, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-7808
Fax: (714) 730-1310
E-mail: pbiggins@us.medical.canon
5. MANUFACTURING SITE
Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan

6. ESTABLISHMENT REGISTRATION
9614698

7. DATE PREPARED
November 6th, 2019

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: Vantage Orian 1.5T, MRT-1550, V6.0 (K193021)
Reference Device: Vantage Galan 3T, MRT-3020, V6.0 with AiCE Reconstruction Processing Unit for MR (K192574)

<table>
<thead>
<tr>
<th>TABLE No. 1: Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>System</td>
</tr>
<tr>
<td>Vantage Orian 1.5T, MRT-1550, V6.0</td>
</tr>
<tr>
<td>Marked By</td>
</tr>
<tr>
<td>510(k) Number</td>
</tr>
<tr>
<td>Clearance Date</td>
</tr>
</tbody>
</table>

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 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.

AiCE is an optional noise reduction algorithm that improves image quality and reduces thermal noise by employing Deep Convolutional Neural Network methods. AiCE is designed to remove Gaussian distributed noise in MR images for reducing contributions of thermal noise. In order to train a DCNN that can learn a model that represents thermal noise, the training datasets are created by adding Gaussian noise of different amplitudes to high-SNR images acquired with large number of averages. The device is targeted for Brain and knee regions. This software and its associated hardware are used on Canon MRI systems that are designed to communicate with the AiCE Reconstruction Processing Unit for MR.

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 1.5T, MRT-1550, V6.0 with AiCE Reconstruction Processing Unit for MR is comparable to the current 1.5T Vantage Orian MRI System (K193021), cleared June 3rd, 2020 with the following modifications.

18. SUMMARY OF CHANGE(S)
   This submission is to report the following software functionalities have been added:

   **Summary of Hardware Changes:**
   - AiCE Reconstruction Processing Unit for MR

   **Summary of Software Changes:**
   - **AiCE:** Advanced Intelligent Clear-IQ Engine (AiCE) is a newly-added optional noise reduction algorithm that improves image quality and reduces thermal noise by employing deep convolutional neural network methods. The device is targeted for brain and knee regions and is MR system independent, meaning that this software and its associated hardware are used on Canon MRI systems that are designed to communicate with the AiCE Reconstruction Processing Unit for MR.
19. SAFETY PARAMETERS

<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device: Vantage Orian 1.5T, MRT-1550, V6.0 with AiCE Reconstruction Processing Unit for MR</th>
<th>Predicate Device: Vantage Orian 1.5T, MRT-1550, V6.0 (K193021)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Static field strength</td>
<td>1.5T</td>
<td>1.5T</td>
<td>Same</td>
</tr>
<tr>
<td>Operational Modes</td>
<td>Normal and 1st Operating Mode</td>
<td>Normal and 1st Operating Mode</td>
<td>Same</td>
</tr>
<tr>
<td>i. Safety parameter display</td>
<td>SAR, dB/dt</td>
<td>SAR, dB/dt</td>
<td>Same</td>
</tr>
<tr>
<td>ii. Operating mode access</td>
<td>Allows screen access to 1st level operating mode</td>
<td>Allows screen access to 1st level operating mode</td>
<td>Same</td>
</tr>
<tr>
<td>Potential emergency</td>
<td>Shutdown by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects</td>
<td>Shutdown by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects</td>
<td>Same</td>
</tr>
<tr>
<td>condition and means provided for shutdown</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
Risk Management activities for new software functionalities 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 (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 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

- IEC60601-1-2 (2014)
- IEC60601-1-6 (2010), Amd.1 (2013)
- IEC60825-1 (2007)
- NEMA MS 1 (2008)
- NEMA MS 2 (2008)
- NEMA MS 3 (2008)
- NEMA MS 4 (2010)
- NEMA MS 5 (2010)

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. Additionally, a human observer study was conducted with 6 board certified radiologists and 160 image data sets 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.

In order to quantify the increase in SNR with AiCE over standard protocols, SNR measurements of sample clinical brain and knee images were obtained. Additionally, contrast was measured using the absolute signal intensity differences between two tissues. The results of the testing demonstrated that AiCE both increased SNR and maintained contrast.

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, referenced in this submission. Canon Medical Systems Corporation believes that the changes incorporated into the Vantage Orian 1.5T, MRT-1550, V6.0 with AiCE Reconstruction Processing Unit for MR are substantially equivalent to the previously cleared predicate device.

26. CONCLUSION
The modifications incorporated into the Vantage Orian 1.5T, MRT-1550, V6.0 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, phantom imaging, 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.