Canon Medical Systems Corporation
% Orlando Tadeo Jr
Sr. Manger, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
Tustin, California 92780

August 20, 2024

Re: K241496
Trade/Device Name: Vantage Galan 3T, MRT-3020, V10.0 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 24, 2024
Received: May 28, 2024

Dear Orlando Tadeo Jr:

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,

Ningzhi Li -S

for
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.

Submission Number *(if known)*

K241496

Device Name

Vantage Galan 3T, MRT-3020, V10.0 with AiCE Reconstruction Processing Unit for MR

Indications for Use *(Describe)*

Vantage Galan 3T 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.

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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 Galan 3T, MRT-3020, V10.0 with AiCE Reconstruction Processing Unit for MR**
Model Number:	**MRT-3020**

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**

   May 24, 2024

8. **DEVICE NAME**

   Vantage Galan 3T, MRT-3020, V10.0 with AiCE Reconstruction Processing Unit for MR

9. **TRADE NAME**

   Vantage Galan 3T, MRT-3020, V10.0 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 Galan 3T, MRT-3020, V9.0 with AiCE Reconstruction Processing Unit for MR (K230355)

System	Predicate Device
	Vantage Galan 3T, MRT-3020, V9.0 with AiCE Reconstruction Processing Unit for MR
Marketed By	Canon Medical Systems USA, Inc.
510(k) Number	K230355
Clearance Date	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 Galan (Model MRT-3020) is a 3 Tesla Magnetic Resonance Imaging (MRI) System, previously cleared under K230355. 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.

18. SUMMARY OF CHANGE(S)

This submission is to report the following changes:

Summary of Hardware Changes:

- **Magnet:** New magnet (inhouse) is applied.
- **Gradient coil:** New gradient coil is applied.
- **Real-time Platform:** Real-time Platform is a new system architecture designed around new Real time Manager (RTM) and it provides stable system performance with highspeed processing by RTM.

Summary of Software Changes:

- **4D Flow:** 4D Flow Application provides the function of visualization of blood flow conditions by combining with external analytical software. Quantitative analysis such as streamline, path line, and velocity is available. Moreover, either Cine or Retro can be used together in PS3D, and PS images with time-phase information can be obtained.
- **Zoom DWI:** Zoom DWI Application offers diffusion images of smaller FOV size by selective excitation and outer volume suppression (OVS). This application proposed to remove the distortion and the aliasing artifact in PE direction.
- **3D-QALAS:** 3D-QALAS (3D-quantification using an interleaved Look-Locker acquisition sequence with T2 preparation pulse) is a scan technique that acquires signals with FFE3D using T2prep pulse and IR pulse in combination. External analytical software is required for quantitative analysis.

Summary of Accessory Changes:

- **Uninterruptible Power-supply System Kit:** This option enables to protect storage such as HDDs and SSDs by continuing to power the HOST-PC and SERVER-PC of the MRI system in the event of a power outage.

19. SAFETY PARAMETERS

Item	Subject Device: Vantage Galan 3T, MRT-3020, V10.0 with AiCE Reconstruction Processing Unit for MR	Predicate Device: Vantage Galan 3T, MRT-3020, V9.0 with AiCE Reconstruction Processing Unit for MR (K230355)	Notes
Static field strength	3T	3T	Same
Operational Modes	Normal and 1st Operating Mode	Normal and 1st Operating Mode	Same

Item	Subject Device: Vantage Galan 3T, MRT-3020, V10.0 with AiCE Reconstruction Processing Unit for MR	Predicate Device: Vantage Galan 3T, MRT-3020, V9.0 with AiCE Reconstruction Processing Unit for MR (K230355)	Notes
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, K230355.

21. INDICATIONS FOR USE

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

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.

4D Flow: 4D Flow provides the function of visualization of blood flow conditions by combining with external analytical software. Bench testing included velocity measurement in a phantom with known flow values. Additionally, images in volunteers demonstrated velocity stream lines.

Zoom DWI: Zoom DWI offers diffusion images of smaller FOV size by selective excitation and outer volume suppression (OVS). Zoom DWI was evaluated utilizing phantom images and representative volunteer images to confirm that Zoom DWI is effective for suppressing wraparound artifacts, reducing image distortion, providing accurate ADC values.

3D-QALAS: 3D-QALAS (3D-quantification using an interleaved Look-Locker acquisition sequence with T2 preparation pulse) is a scan technique that acquires signals with FFE3D using T2prep pulse and IR pulse in combination. External analytical software is required for quantitative analysis. Bench testing included scanning multiple volunteers and comparing, by three experienced reviewers, the resulting multiple weighted images on image quality metrics such as overall contrast and signal strength against reference images published in the literature.

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 Galan 3T, MRT-3020, V10.0, 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 Galan 3T, MRT-3020, V10.0, 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 Galan 3T, MRT-3020, V10.0, 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.