January 7, 2025

Canon Medical Systems Corporation
% Blake Stacy
Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
Tustin, California 92780

Re: K243335
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: October 24, 2024
Received: October 24, 2024

Dear Blake Stacy:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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.

Submission Number *(if known)*

K243335

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.

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 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

Contact Person
Blake Stacy
Manager, Regulatory Affairs, Canon Medical Systems USA, Inc.
2441 Michelle Drive, Tustin, CA 92780
Phone: (626) 319-9444
Fax: (714) 730-1310
E-mail: bstacy@us.medical.canon

Official Correspondent/U.S. Agent
Oralndo Tadeo, Jr.
Director, Regulatory Affairs, Canon Medical Systems USA, Inc.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 669-7459
Fax: (714) 730-1310
E-mail: otadeo@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**

   October 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, V10.0 with AiCE Reconstruction Processing Unit for MR (K241496)

System	Predicate Device
	Vantage Galan 3T, MRT-3020, V10.0 with AiCE Reconstruction Processing Unit for MR
Marketed By	Canon Medical Systems USA, Inc.
510(k) Number	K241496
Clearance Date	August 20, 2024

15. REFERENCE DEVICE

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

System	Reference 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

16. REASON FOR SUBMISSION

Modification of a cleared device

17. SUBMISSION TYPE

Traditional 510(k) Premarket Notification

18. DEVICE DESCRIPTION

The Vantage Galan (Model MRT-3020) is a 3 Tesla Magnetic Resonance Imaging (MRI) System, previously cleared under K241496. 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.

19. SUMMARY OF CHANGE(S)

This submission is to report the following changes:

Standard Gradient: Standard gradient system (STD), compatible with the hardware and software updates introduced in the predicate submission, has been added to the subject Vantage Galan 3T, MRT-3020, V10.0 system. The gradient amplifier for the STD system is the same one that is used in the reference device (K230355).

Precise IQ Engine (PIQE): PIQE is a Deep Learning based technique that generates higher in-plane matrix images from low matrix images while mitigating the ringing artifact. PIQE has been extended to multiple scan families, weightings, and additional anatomical areas.

System Software: Minor updates were made to the system software.

20. 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, V10.0 with AiCE Reconstruction Processing Unit for MR (K241496)	Notes
Static field strength	3T	3T	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, V10.0 with AiCE Reconstruction Processing Unit for MR (K241496)	Notes
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

21. IMAGING PERFORMANCE PARAMETERS

No change from the predicate submission, K241496.

22. 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.

**Note: No change from the predicate submission, K241496.*

23. 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, V10.0 with AiCE Reconstruction Processing Unit for MR (K241496). A declaration of conformity with design controls is included in this submission.

24. 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)

25. 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.

PIQE Performance Testing - Bench

PIQE (Precise IQ Engine) for MR was not altered from the previously cleared version, but was extended to include additional scanning techniques, image weightings, and anatomical locations. PIQE underwent the same performance testing established in K230355 and applied to each of the new anatomical regions. This testing included bench testing, performed on typical clinical images from Body, Breast, Cardiac, MSK, and Neuro, wherein 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 were evaluated. Comparing images with PIQE at various scaling factors to standard clinical techniques, such as zero-padding interpolation and typical clinical filters, confirmed that PIQE generates images with sharper edges while mitigating the smoothing and ringing effects and maintaining similar or better contrast and SNR.

PIQE Performance Testing - Clinical Image Review Study

Additionally, a multi-site, randomized, blinded, clinical image review study was conducted with 14 USA board-certified radiologists and cardiologists (3 per anatomy). Using the conventional method (matrix expansion with Fine Reconstruction and processing with typical clinical filter) as a reference, the images reconstructed with either the conventional method or the PIQE method were randomized, blinded to the reviewers, and scored by 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. A total of 106 unique subjects, from two sites in USA and one in Japan, were scanned in body, breast, cardiac, MSK, or neuro regions to provide the test data sets (separate from the training data sets) using Vantage Galan 3T and anatomy-appropriate coils, comprising a total of 480 scans, in multiple orientations, and multiple contrast weightings within the multiple families of pulse sequences. Reviewer scoring data was analyzed for reviewer agreement and differences between reconstruction techniques using Gwet's Agreement Coefficient and Generalized Estimating Equations, respectively. The resulting reconstructions were all scored on average at, or above, clinically acceptable. Exhibiting a strong agreement at the "good" and "very good" level for all IQ metrics, the reviewers' scoring confirmed that (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; and (d) PIQE benefits can be obtained on regular clinical protocols without requiring acquisition parameter adjustment.

Although the dataset of this multinational study includes subjects from outside the USA, the population is expected to be representative of the intended US population as it pertains to the intended use of the PIQE product. PIQE is an image post-processing algorithm that is not disease-specific and is not dependent on factors that would be relevant for scan acquisition or diagnosis-specific algorithms. The PIQE algorithm is not directly dependent on acquisition parameters that might be affected by population variation (such as body habitus). The study design for this submission is based on reconstructing each k-space acquisition multiple times (both with and without PIQE) such that all comparisons are internal, with each subject as its own control. Therefore, patient-variable influences would not be considered a factor. For PIQE, where matrix expansion (pixel size) and edge sharpness are key, the relevant characteristics are primarily tissue structure, feature definition, and edge definition; and to some extent matrix size and FOV. Thus, related to the anatomies of interest in this study, relevant features do not vary significantly from country to country. Further, even if the internal structures themselves are different, or differently distributed, across countries, the edge definition of such structures are not expected to vary differently patient-to-patient due to nationality.

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.

26. SUBSTANTIAL EQUIVALENCE

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.

27. 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 as safe and effective for its intended use.