Canon Medical Systems Corporation
% Ms. Janine F. Reyes
Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
TUSTIN CA 92780

March 2, 2020

Re: K192506
Trade/Device Name: Vantage Galan 3T, MRT-3020, V6.0
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: January 21, 2020
Received: January 22, 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192506

Device Name
Vantage Galan 3T, MRT-3020, V6.0

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.

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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, V6.0**
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**
   September 10th, 2019

8. **DEVICE NAME**
   Vantage Galan 3T, MRT-3020, V6.0

9. **TRADE NAME**
   Vantage Galan 3T, MRT-3020, V6.0

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 (system): Vantage Galan 3T, MRT-3020/A7, V5.0 (K181593)
    Reference Device (system): Vantage Galan 3T, MRT-3020 (K162183), Vantage Galan 3T, MRT-3020/A9 (K183657), Vantage Orian 1.5T, MRT-1550 (K182282)

	Subject Device	Predicate Device	Reference Device	Reference Device	Reference Device
System	Vantage Galan 3T, MRT-3020, V6.0	Vantage Galan 3T, MRT-3020/A7, V5.0	Vantage Galan 3T, MRT-3020, V4.0	Vantage Galan 3T, MRT-3020/A9, V5.0	Vantage Orian 1.5T, MRT-1550, V4.5
Marketed By	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.
510(k) Number	This Submission	K181593	K162183	K183657	K182282
Clearance Date		August 13, 2018	November 25, 2016	March 15, 2019	October 19, 2018

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 K181593. 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 software functionalities have been added:

Summary of Hardware Changes:

- **New Cover Design**
- **Optional Dockable/Detachable Table**

Summary of Software Changes:

- **New SAR:** New calculation method is applied.
- **Compressed SPEEDER (Compressed Sensing)*:**
    - This application allows accelerated fast scan of the brain, cervical spine, thoracic spine, lumbar spine, shoulder, knee, foot, ankle, elbow and wrist. Compressed SPEEDER combines parallel imaging by using multi-sensitivity map and compressed sensing.
    - Compressed SPEEDER feature allows acceleration factors for shorter scan times or higher resolution in FSE2D imaging based upon the principle of Compressed Sensing in combination with parallel imaging.
- **T2 Map Using Pre-Contrast Pulses:** ECG gating or peripheral pulse gating is used in scanning with FFE2D sequences, and different Pre-contrast pulses are used to obtain multiple TEeff images.
- **CP Mode (quadrature transmit mode):** has been added.

Labeling Changes:

- **Adaptive Scan Mode:** The function name of “Limited Scan Mode” has been changed to “Adaptive Scan Mode”.

**Note: Compressed SPEEDER should not be used for contrast-agent-enhanced imaging.*

19. SAFETY PARAMETERS

Item	Subject Device: Vantage Galan 3T, MRT-3020, V6.0	Predicate Device: Vantage Galan 3.0T, MRT-3020/A7, V5.0	Notes
Static field strength	3T	3T	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)	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	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, K181593.

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 new software functionalities and hardware changes 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/A7, V5.0 (K181593). 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
- IEC60601-1-2 (2014)
- IEC60601-1-6 (2010), Amd.1 (2013)
- IEC60601-2-33 (2010), Amd.1 (2013), Amd.2 (2015)
- IEC60825-1 (2007)
- IEC62304 (2006), Amd.1 (2015)
- IEC62366 (2007), Amd.1 (2014)
- NEMA MS 1 (2008)
- NEMA MS 2 (2008)
- NEMA MS 3 (2008)
- 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.

MR image quality metrics were performed, utilizing phantoms and volunteer images, to assess Compressed SPEEDER with regards to SNR, unfolding error artifacts and performance in all the phase encode directions. It was concluded that Compressed SPEEDER met all acceptance criteria.

Additionally, representative images, reviewed by American Board Certified Radiologists, were obtained using the subject device. Reviewers provided detailed assessments of image degradation, diagnostic performance, lesion conspicuity, and clinical utility. It was confirmed that Compressed SPEEDER images were of diagnostic quality.

T2 Map Using Pre-Contrast Pulses was evaluated utilizing phantom and volunteer images. It was concluded that T2 maps can be generated using the data acquired using pre-contrast pulses.

New SAR calculation method was evaluated by imaging and modeling a phantom of known dimension and electromagnetic properties in combination with volunteer imaging. It was concluded that the new SAR calculation method is substantially equivalent to the predicate device as demonstrated by the results of the above testing.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

25. SUBSTANTIAL EQUIVALENCE

Canon Medical Systems Corporation believes that the Vantage Galan 3T, MRT-3020, V6.0 Magnetic Resonance Imaging (MRI) System is substantially equivalent to the previously cleared predicate device, Vantage Galan 3T, MRT-3020/A7, V5.0, referenced in this submission. Canon Medical Systems Corporation believes that the changes incorporated into the Vantage Galan 3T, MRT-3020, V6.0 are substantially equivalent to the previously cleared predicate device.

26. CONCLUSION

The modifications incorporated into the Vantage Galan 3T, MRT-3020, V6.0 do not change the indications for use or the intended use of the device. Based upon bench testing, 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.