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

August 13, 2018

Re: K181593
Trade/Device Name: Vantage Galan 3T, MRT-3020/A7, V5.0
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: June 15, 2018
Received: June 18, 2018

Dear Janine 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
k181593

Device Name
Vantage Galan 3T, MRT-3020/A7, V5.0

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.

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

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CANON MEDICAL SYSTEMS USA, INC.

k181593

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/A7, V5.0**
Model Number:	**MRT-3020/A7**

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

June 15th, 2018

8. DEVICE NAME

Vantage Galan 3T, MRT-3020/A7, V5.0

9. TRADE NAME

Vantage Galan 3T, MRT-3020/A7, V5.0

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, V4.6

System	Subject	Predicate Device
	Vantage Galan 3T, MRT-3020/A7, V5.0	Vantage Galan 3T, MRT-3020, V4.6
Marketed By	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.
510(k) Number	This Submission	K173382
Clearance Date		January 26, 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/A7) is a 3 Tesla Magnetic Resonance Imaging (MRI) System, previously cleared under K173382. 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:

- **Software change from V4.6 to V5.0**
- **Limited Scan Mode:** Operator can set SAR operating mode and upper limit of B1+rms. Scan parameters are calculated so that SAR and B1+rms do not exceed set limits.
- **KneeLine+:** When the basic planes of the knee are to be scanned, this application makes it possible to set the slice plane more easily than before. After a 3D image is acquired, it is used to obtain the three planes (sagittal, axial and coronal) after adjusting the angle of the knee. The obtained images can be used to set the plane of the positioning ROI. If necessary, the orientation and position of the detected basic planes can be adjusted by scan positioning operation in the Scan Plan (Locator) window.
- **SUREVOI Knee:** Using a 3D image as an input, the region of the knee is determined and the VOI for shimming scan, map scan, or presaturation is detected. The detected VOI can be used for knee scan positioning. If necessary, the VOI can be checked and the orientation and position of the VOI can be adjusted in the Scan Plan (Locator) window.
- **k-t SPEEDER:** Estimated sensitivity data is calculated using the sensitivity data for each coil obtained during scanning, and the folded image obtained by skipped image acquisition is unfolded. A speedup factor of 2 to 8 can be achieved depending on the skipping ratio.
- **R-wave Monitoring:** The range of the R-R intervals for data acquisition can be determined. If the R-R intervals at the time of data acquisition is out of range, data acquisition is performed again.
- **SpineLine+:** New spinal plane detection algorithm improves detection rate for patients.
- **Sequence Enhancements:**
  - **WFS DIXON (Water Fat Separation):** WFS option previously applicable to FE3D sequences is added to FSE2D sequences.
  - **Quick Star:** Data acquisition is started from the center of the k-space in a radial pattern in the in-plane direction in the k-space and in a Cartesian pattern in the slice direction. Because the data near the center of the k-space is acquired repeatedly, data acquisition with Quick Star is relatively unaffected by motion.
  - **Fast 3D Mode:** Fast 3D mode can be used to increase imaging efficiency. Two types of Fast 3D mode (Multiple and Wheel) are available. Multiple is technique for acquiring two parallel SE lines continuously in a single shot. Wheel is technique for

acquiring signals at the center of the k-space in a deformed wheel pattern in the PE-SE plane.

- **2D-RMC (Real-time Motion Correction) for EPI:** 2D Real-time Motion Correction is available for Diffusion Weighted Imaging to mitigate respiratory motion artifacts of abdominal examination. 2D-RMC option previously applicable to FASE3D and FFE3D sequences is added to EPI sequences.

19. SAFETY PARAMETERS

Item	Subject Device: Vantage Galan 3T, MRT-3020/A7, V5.0	Predicate Device: Vantage Galan 3T, MRT-3020, V4.6	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)	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	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, K173382.

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)
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- 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 changes to the previously cleared indication, K173382*

22. SUMMARY OF DESIGN CONTROL ACTIVITIES

Risk Management activities for new software functionalities and pulse sequences 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, V4.6 (K173382). 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 (2005), Amd.1 (2012)
- IEC60601-1-2 (2007)
- IEC60601-1-8 (2006), Amd.1 (2012)
- IEC60601-2-33 (2010), Amd.1 (2013)
- IEC60825-1 (2007)
- IEC62304 (2006)
- 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

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/A7, V5.0 Magnetic Resonance Imaging (MRI) System is substantially equivalent to the previously cleared predicate device, Vantage Galan 3T, MRT-3020, V4.6, referenced in this submission. Canon Medical

Systems Corporation believes that the changes incorporated into the Vantage Galan 3T, MRT-3020/A7, V5.0 are substantially equivalent to the previously cleared predicate device.

26. CONCLUSION

The modifications incorporated into the Vantage Galan 3T, MRT-3020/A7, V5.0 software 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.