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/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,

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure
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.
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 Galan 3T, MRT-3020/A9, V5.0</td>
</tr>
<tr>
<td>Model Number:</td>
<td>MRT-3020/A9</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

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5. **MANUFACTURING SITE**
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   1385 Shimoishigami  
   Otawara-shi, Tochigi 324-8550, Japan

6. **ESTABLISHMENT REGISTRATION**
   9614698

7. **DATE PREPARED**
   December 21, 2018

8. **DEVICE NAME**
   Vantage Galan 3T, MRT-3020/A9, V5.0

9. **TRADE NAME**
   Vantage Galan 3T, MRT-3020/A9, 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/A7, V5.0 (K181593)

<table>
<thead>
<tr>
<th>System</th>
<th>Subject</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vantage Galan 3T, MRT-3020/A9, V5.0</td>
<td>Vantage Galan 3T, MRT-3020/A9, V5.0</td>
</tr>
<tr>
<td>Marketed By</td>
<td>Canon Medical Systems USA, Inc.</td>
<td>Canon Medical Systems USA, Inc.</td>
</tr>
<tr>
<td>510(k) Number</td>
<td>This Submission</td>
<td>K181593</td>
</tr>
<tr>
<td>Clearance Date</td>
<td></td>
<td>August 13, 2018</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 Galan (Model MRT-3020/A9) 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:
- Maximum gradient field strength has been changed from 45mT/m to 100mT/m.
- Patient aperture size has been changed from 71 cm to 63 cm.
- Gradient coil and QD whole body transmit coil have been changed.

Summary of Software Changes:
- CP mode (quadrature transmit mode) has been added.

No other changes from the previously cleared indication (K181593).

19. SAFETY PARAMETERS

<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device: Vantage Galan 3T, MRT-3020/A9, V5.0</th>
<th>Predicate Device: Vantage Galan 3T, MRT-3020, V4.6</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Static field strength</td>
<td>3T</td>
<td>3T</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 requirements</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 condition and means provided for shutdown</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>
</tbody>
</table>

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.
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No changes to the previously cleared indication, K181593.

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

- IEC60825-1 (2007)
- IEC62304 (2006)
- 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/A9, V5.0 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/A9, V5.0 are substantially equivalent to the previously cleared predicate device.

26. CONCLUSION

The modifications incorporated into the Vantage Galan 3T, MRT-3020/A9, V5.0 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.