Canon Medical Systems Corporation   March 10, 2021
℅ Ms. Janine Reyes
Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K210164
       Trade/Device Name: Vantage Elan 1.5T, MRT-2020, V6.0
       Regulation Number: 21 CFR 892.1000
       Regulation Name: Magnetic resonance diagnostic device
       Regulatory Class: Class II
       Product Code: LNH
       Dated: January 19, 2021
       Received: January 21, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210164

Device Name
Vantage Elan 1.5T, MRT-2020, V6.0

Indications for Use *(Describe)*

Vantage Elan 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.

FORM FDA 3881 (6/20)   Page 1 of 1   PSC Publishing Services (301) 443-6740   EF

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 Elan 1.5T, MRT-2020, V6.0**
Model Number:	**MRT-2020**

2. SUBMITTER'S NAME

Canon Medical Systems Corporation

1385 Shimoishigami

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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**

   January 15, 2021

8. **DEVICE NAME**

   Vantage Elan 1.5T, MRT-2020, V6.0

9. **TRADE NAME**

   Vantage Elan 1.5T, MRT-2020, 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: Vantage Elan 1.5T, MRT-2020, M-Power GX (K171597)

    Reference Device: Vantage Orian 1.5T, MRT-1550, V6.0 (K193021)

    TABLE No. 1: Primary Predicate Device

System	Subject Device	Predicate Device	Reference Device
	Vantage Elan 1.5T, MRT-2020, V6.0	Vantage Elan 1.5T, MRT-2020, M-Power GX	Vantage Orian 1.5T, MRT-1550, V6.0
Marketed By	**Canon Medical Systems USA, Inc.**	Canon Medical Systems USA, Inc.	Canon Medical Systems USA, Inc.
510(k) Number	**This Submission**	K171597	K193021
Clearance Date		July 21, 2017	June 3, 2020

15. **REASON FOR SUBMISSION**
Modification of a cleared device

16. **SUBMISSION TYPE**
Traditional 510(k) Premarket Notification

17. **DEVICE DESCRIPTION**
The Vantage Elan (Model MRT-2020) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System, previously cleared under K171597. 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. The Vantage Elan uses 1.4m short and 4.1 ton light weight magnet. It includes the Pianissimo™ Σ technology (scan noise reduction technology). The design of the gradient coil and the whole body coil of the Vantage Elan provides the maximum field of view of 55 x 55 x 50 cm. The Model MRT-2020/A1 is without secondary cooling system and the Model MRT-2020/A2 is with secondary cooling system.

18. **SUMMARY OF CHANGE(S)**
This submission is to report the following software functionalities have been added:

- **Additional Software Functionalities and Improvements:**

    o **SpineLine+ (Spinal Scan Positioning Support Function):** Provides automatic positioning assistance for spine imaging. SpineLine was previously cleared under K141472. As compared to SpineLine, SpineLine+ offers improved detection of the axial plane along the intervertebral space.

    o **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.

    o ^{SURE}**VOI 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.

    o **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.

    o **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.

    o **Windows 10:** Windows 10 has been applied to V6.0 Software.

- **Sequence Enhancements:**
  - **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.
  - **WFS DIXON (Water Fat Separation):** WFS option previously applicable to FE3D sequences is added to FSE2D sequences.
  - **2D-RMC (Real Time Motion Correction) for EPI:** 2D Real-time Motion Correction is available for Diffusion Weighted Imaging to mitigate respiratory motion artifacts during abdominal examinations. 2D-RMC option is newly applied to EPI sequences (previously applicable to FASE3D and FFE3D).

19. SAFETY PARAMETERS

Item	Subject Device: Vantage Elan 1.5T, MRT-2020, V6.0	Predicate Device: Vantage Elan 1.5T, MRT-2020, M-Power GX	Notes
Static field strength	**1.5T**	1.5T	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, K171597.

21. **INDICATIONS FOR USE**

Vantage Elan 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 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 Elan 1.5T, MRT-2020, M-Power GX (K171597). 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.

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.

WFS DIXON (Water Fat Separation) was evaluated utilizing phantom images. Testing verified that water signals and fat signals are separated in the water image and the fat image, respectively.

2D-RMC (Real Time Motion Correction) for EPI was evaluated utilizing phantom and volunteer images. Testing verified the use of 2DRMC in scanning with SEEPI2D sequence is effective.

MR image quality metrics were performed, utilizing volunteer images, to evaluate SpineLine+, KneeLine+, ^{SURE}VOI Knee, Quick Star, and Fast 3D mode. It was confirmed that these features worked as intended, the images were of diagnostic quality, and the test results met predetermined acceptance criteria.

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 Elan 1.5T, MRT-1550, V6.0 is substantially equivalent to the previously cleared predicate device, Vantage Elan 1.5T, MRT-1550, M-Power GX, referenced in this submission. Canon Medical Systems Corporation believes that the changes incorporated into the Vantage Elan 1.5T, MRT-1550, V6.0 are substantially equivalent to the previously cleared predicate device.

26. **CONCLUSION**

The modifications incorporated into the Vantage Elan 1.5T, MRT-1550, 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.