DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 25, 2016

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

Re: K162183
Trade/Device Name: Vantage Galan 3T, MRT-3020, V4.0
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 14, 2016
Received: November 15, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162183

Device Name
Vantage Galan 3T, MRT-3020, V4.0

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

Contrast agent use is restricted to the approved drug indications. 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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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, V4.0**
Model Number:	**MRT-3020**

2. SUBMITTER'S NAME:

Toshiba Medical Systems Corporation (TMSC)
1385 Shimoishigami
Otawara-Shi, Tochigi-ken, Japan 324-8550

3. OFFICIAL CORRESPONDENT:

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4. CONTACT PERSON, U.S. AGENT AND ADDRESS:

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5. MANUFACTURING SITE:

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6. ESTABLISHMENT REGISTRATION:

9614698

7. Date Prepared:

August 2, 2016

8. DEVICE NAME:

Vantage Galan 3T, MRT-3020, V4.0

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9. **TRADE NAME(S):**
   Vantage Galan 3T, MRT-3020, V4.0

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:**
    Primary Predicate Device (system): Vantage Titan 3T, MRT-3010, V3.5
    Reference Predicate Device (added software functionalities): Vantage Titan 1.5T, MRT-1510, V3.6

	Subject	Primary Predicate	Reference Predicate
System	Vantage Galan 3T, MRT-3020, V4.0	Vantage Titan 3T, MRT-3010, V3.5	Vantage Titan 1.5T, MRT-1510, V3.6
Marketed By	Toshiba America Medical Systems	Toshiba America Medical Systems	Toshiba America Medical Systems
510(k) Number	This Submission	K152371	K160632
Clearance Date		October 23, 2015	510(k) Pending

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

16. **DEVICE DESCRIPTION**
    The Vantage Galan 3T (Model MRT-3020) is a 3 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Galan 3T uses 1.6m short and 6.4 tons light weight magnet. It includes the Toshiba Pianissimo™ technology (scan noise reduction technology). The design of the gradient coil and the WB coil of the Vantage Galan 3T provides the maximum field of view of 50 x 50 x 45 cm. The 3T Vantage Galan MRI System is comparable to the current 3T Vantage Titan MRI System (K152371), cleared October 23rd, 2015 with the following modifications.

17. **SUMMARY OF HARDWARE CHANGES**
    This submission is to report the following hardware changes have been made:
    - RF system:
      - Maximum RF duty cycle changed from 50% to 100%
      - PURE RF Rx/Tx

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18. SUMMARY OF SOFWARE CHANGES

This submission is to report the following software functionalities have been added:

- Sequence Enhancement:
  - FFE3D:
    - SPAIR - pre-pulse for fat suppression
    - T2 Prep - pre-pulse for T2 weighted contrast
    - mUTE - Ulta short TE T1 weighted sequence with reduced acoustic noise
    - mUTE 4D-MRA - Ultra short TE time resolved MR angiography with reduced acoustic noise
    - 2D-RMC - Two dimensional real-time motion correction
  - MP2RAGE - Images with multiple TI (Inversion time) to create T1 map
  - FSE2D:mEcho - Images with multiple TE (Echo time) to create T2 map
  - FFE2D:mEcho - Images with multiple TE (Echo time) to create T2* map
  - mASTAR - Multiple phase ASL (Arterial Spin Labeling)
  - FASE DWI - Spin Echo based Diffusion Weighted Imaging with reduced acoustic noise
- Enhancement of SPEEDER post-processing
- EasyTech Cardiac – SUREVOI and CardioLine+
- Improvement of SUREECG R-wave detection

19. SAFETY PARAMETERS

Item	Subject Device: Vantage Galan 3T, MRT-3020, V4.0	Predicate Device: Vantage Titan 3T, MRT-3010, V3.5 (K152371)	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))	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33(2010))	Same
Maximum dB/dt	1st operating mode specified in IEC 60601-2-33 (2010)	1st operating mode specified in IEC 60601-2-33 (2010)	Same
Potential emergency condition and means provided for shutdown	Shut down by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Shut down by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Same

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20. IMAGING PERFORMANCE PARAMETERS

No change from the previous predicate submission, K152371.

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

Contrast agent use is restricted to the approved drug indications. When interpreted by a trained physician, these images yield information that can be useful in diagnosis.

No changes to the previously cleared indication, K152371.

22. SUMMARY OF DESIGN CONTROL ACTIVITIES

Hazard analysis has been performed and documentation is included in this submission. PS Risk List 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 submissions (K152371). 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):

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LIST OF APPLICABLE STANDARDS

- IEC60601-1:2005
- IEC60601-1-2:2007
- IEC60601-1-8:2006,Amd.1:2012
- IEC60601-2-33:2010
- 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

Toshiba Medical Systems Corporation believes that the Vantage Galan 3T, MRT-3020, V4.0 Magnetic Resonance Imaging (MRI) System is substantially equivalent to the previously cleared predicate device referenced in this submission. Toshiba Medical Systems Corporation believes that the changes incorporated into the Vantage Galan 3T, MRT-3020, V4.0 are substantially equivalent to the previously cleared predicate device.

26. CONCLUSION

The modifications incorporated into the Vantage Galan 3T, MRT-3020, V4.0 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.

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
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