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

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director Regulatory Affairs/U.S. Agent
2441 Michelle Drive
TUSTIN CA 92780

April 9, 2015

Re: K143008
Trade/Device Name: Vantage Titan 3T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH
Dated: April 6, 2015
Received: April 7, 2015

Dear Mr. Biggins:

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.
Acting 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)* K143008

Device Name

MRT-3010/A5, Vantage Titan 3T

Indications for Use *(Describe)*

Vantage Titan 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. CLASSIFICATION and DEVICE NAME:

Classification Name:	**Magnetic Resonance Diagnostic Device**
Regulation Number:	**90-LNH (Per 21 CFR 892.1000)**
Trade Proprietary Name:	**Vantage Titan 3T**
Model Number:	**MRT-3010/A5**

2. ESTABLISHMENT REGISTRATION: 9614698

3. Toshiba Medical Systems Corporation (TMSC)

1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan

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

U.S. Agent Name:
Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, Ca. 92780
(714) 699-7808

5. MANUFACTURING SITE:

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

6. DATE OF SUBMISSION:

October 17, 2014

7. DEVICE DESCRIPTION:

The Vantage Titan 3T (Model MRT-3010/A5) is a 3 Tesla Magnetic Resonance Imaging (MRI) System and was cleared under K132160. This submission includes WFS (Water Fat Separation) software functionality and the optional subsystem, Saturn Gradient Option.

7.1 SUMMARY OF HARDWARE CHANGES

Saturn Gradient Option with increased gradient field strength of 45mT/m.

7.2 SUMMARY OF SOFTWARE CHANGES

a. WFS (Water Fat Separation) to provide water dominant images and fat dominant images.

8. SAFETY PARAMETERS

Item	Vantage Titan 3T, V2.50 (subject device)	Vantage Titan 3T, V2.30 K132160 (Predicate Device)	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

8. IMAGING PERFORMACE PARAMETERS

No change from the previous predicate submission (K132160).

9. INTENDED USE

Vantage Titan 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 (K132160).

10. SUMMARY OF DESIGN CONTROL ACTIVITIES

PS Risk List for software of changing packages are attached. The test methods used are the same as those submitted in the previously cleared submissions (K132160). A declaration of conformity with design controls is included in this submission.

11. TRUTHFUL AND ACCURACY CERTIFICATION

A certification of the truthfulness and accuracy of the Vantage Titan 3T described in this submission is provided in this submission.

12. SUBSTANTIAL EQUIVALENCE

Toshiba Medical Systems Corporation believes that the Vantage Titan 3T (model MRT-3010/A5) Magnetic Resonance Imaging (MRI) System is substantially equivalent to the previously cleared predicate devices referenced in this submission.

Testing was done in accordance with applicable recognized consensus standards as listed below.

List of Applicable Standards

- IEC60601-1:2005
- IEC60601-1-2:2007
- IEC60601-1-8:2003,Amd.1:2006
- IEC60601-2-33:2010
- IEC60825-1: 2007
- IEC62304:2006
- IEC62366:2007
- NEMA MS-1:2008
- NEMA MS-2:2008
- NEMA MS-3:2008
- NEMA MS-4:2010
- NEMA MS-5:2010
- NEMA PS 3.1-20 (2011)

Additional testing for WFS (Water Fat Separation) pulse sequence and software functionality included both phantom studies and representative volunteer images. This testing demonstrated that the software performed as specified and did not raise new issues of safety and effectiveness. The additional software packages are work flow improvements and their performance was demonstrated to be equal to or better than the current methods for obtaining the same results.