



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

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

October 23, 2015

Re: K152371  
Trade/Device Name: Vantage Titan 3T (MRT-3010)  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance diagnostic device  
Regulatory Class: II  
Product Code: LNH  
Dated: August 18, 2015  
Received: August 21, 2015

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

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

## Indications for Use

510(k) Number (if known)

K152371

Device Name

Vantage Titan 3T, MRT-3010

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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**1. CLASSIFICATION and DEVICE NAME:**

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

**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:**

**Contact Person**

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Manager, Regulatory Affairs  
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**U.S. Agent Name:**

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Director, Regulatory Affairs  
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**5. MANUFACTURING SITE:**

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

**6. DATE OF SUBMISSION:**

August 11<sup>th</sup>, 2015

**7. DEVICE DESCRIPTION:**

The Vantage Titan 3T (Model MRT-3010) is a 3 Tesla Magnetic Resonance Imaging (MRI) System and was cleared under K143008. This submission will include the following software functionalities: UTE (Ultra Short TE), MP-RAGE, T2:mEcho, T2\*:mEcho, Improvements to MRS, Multi b-value DWI, SpineLine, NeuroLine+, SureVOI, 2D Real-time Motion Correction (2D-RMC) and eFSBB.

**7.1 SUMMARY OF HARDWARE CHANGES**

No change from previous predicate submission, K143008.

**7.2 SUMMARY OF SOFTWARE CHANGES**

- a. UTE (Ultra Short TE) pulse sequence
- b. MP-RAGE pulse sequence
- c. T2:mEcho pulse sequence
- d. T2\*:mEcho pulse sequence
- e. Improvements to MRS
- f. Multi b-value DWI
- g. SpineLine (automatic positioning assistance for spine)
- h. NeuroLine+ (automatic positioning assistance for neuro)
- i. SureVOI (automatic cardiac planning assistance)
- j. 2D Real-time Motion Correction (2D-RMC)
- k. eFSBB (new phase-enhanced filter)

**8. SAFETY PARAMETERS**

Item	Vantage Titan 3T, V3.5 <b>(Subject Device)</b>	Vantage Titan 3T, V2.50 K143008 <b>(Predicate Device)</b>	Notes
Static field strength	3T	3T	Same
Operational Modes	Normal and 1 <sup>st</sup> Operating Mode	Normal and 1 <sup>st</sup> Operating Mode	Same
i. Safety parameter display	SAR dB/dt	SAR dB/dt	Same
ii. Operating mode access requirements	Allows screen access to 1 <sup>st</sup> level operating mode	Allows screen access to 1 <sup>st</sup> level operating mode	Same
Maximum SAR	4W/kg for whole body (1 <sup>st</sup> operating mode specified in IEC 60601-2-33(2010))	4W/kg for whole body (1 <sup>st</sup> 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

Item	Vantage Titan 3T, V3.5 (Subject Device)	Vantage Titan 3T, V2.50 K143008 (Predicate Device)	Notes
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 PERFORMANCE PARAMETERS**

No change from the previous predicate submission (K143008).

**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 (K143008).

**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 (K143008). 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) 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

Based upon bench testing, phantom image studies and sample clinical images Toshiba Medical Systems Corporation believes this system has characteristics that are compatible with currently marketed devices and has proven substantively that this system performed as specified and did not raise new issues of safety and effectiveness. Furthermore, this system does not offer new intended or indicated use when compared to the predicate. Based upon this information, Toshiba believes that it has established substantial equivalence to this device and the predicate.