JUN - 1 2012

K120638

510(k) SUMMARY AND EFFECTIVENESS

1. DEVICE NAME:

Generic Name:	Magnetic Resonance Diagnostic Device
Model Name:	MRT-1504/U4
Trade/ Proprietary Name:	Vantage Titan

2. ESTABLISHMENT REGISTRATION: 2020563

3. U.S AGENT INFORMATION:

U.S. Agent Name:	Paul Biggins (714) 730-5000
Establishment Name and Address:	Toshiba America Medical Systems, Inc. 2441 Michelle Drive Tustin, Ca. 92780

4. MANUFACTURING SITE: Toshiba Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550
Japan

5. DATE OF SUBMISSION: February 29, 2012

6. DEVICE DESCRIPTION

The new Vantage Titan (Model MRT-1504/U4) MRI System is comparable to the current 1.5T Vantage Titan MRI System. The Vantage Titan uses the same magnet as the current Vantage Titan (K080038). However, the following modifications have been added: a redefinition of gradient strength, magnet cover and cabinet's configuration changes. In addition, two applications software: Diffusion Tensor Tractography (DTT), and PaceMaker.

7. SUMMARY OF MAJOR HARDWARE CHANGES

a. Gradient Strength (redefinition)
b. Magnet Cover
c. Changes to the cabinet configuration

8. SUMMARY OF MAJOR SOFTWARE CHANGES

a. Addition of 2 applications software
   i. Diffusion Tensor Tractography (DTT)
   ii. PaceMaker (FBI with Auto ECG)

9. SAFETY PARAMETERS

	New Vantage Titan (Subject device)	Vantage Titan (Predicate, K080038)	Vantage Titan HSR (Predicate, K112003)
a. Static field strength:	1.5T	1.5 T	1.5T
b. Peak and A-weighted acoustic noise:	106.2 dB (A-weighed) 115.4 dB(peak)	105.7dB (A-weighted) 115.7dB (peak)	113.0 dB (A-weighted) 121.6 dB (peak)
c. Operational modes:	1st operating mode	1st operating mode	1st operating mode
i. Safety parameter display:	SAR, dB/dt	SAR, dB/dt	SAR, dB/dt
ii. Operating mode access requirements:	Allows screen access to 1st level operating mode	Allows screen access to 1st level operating mode	Allows screen access to 1st level operating mode
d. Maximum SAR	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33 (2002))	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33 (2002))	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33 (2002))
e. Maximum dB/dt	<1st operating mode specified in IEC 60601-2-33 (2002)	<1st operating mode specified in IEC 60601-2-33 (2002)	<1st operating mode specified in IEC 60601-2-33 (2002)
f. Potential emergency conditions and means provided for shutdown:	Shut down by Emergency Ramp Down Unit for collision hazard by ferromagnetic objects	Shut down by Emergency Ramp Down Unit for collision hazard by ferromagnetic objects	Shut down by Emergency Ramp Down Unit for collision hazard by ferromagnetic objects
Biocompatibility of materials	Confirmed for electrodes and accessories for wireless gating	Not applicable	Confirmed for electrodes and accessories for wireless gating

10. IMAGING PERFORMACE PARAMETERS

No change from the previous predicate submission (K080038).

11. INTEDED USE

The MRI system is 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. In addition, this system supports non-contrast 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 (K080038).

12. DESIGN CHANGE

The Vantage Titan MRI System is comparable to the existing 1.5T Vantage Titian MRI System (K080038) and 1.5T Vantage Titan HSR MRI System (K112003) with the following modifications.

a. Definition of gradient strength has been changed.
b. Magnet covers have been changed.
c. Cabinet configurations have been changed.
d. Two application software have been added
    1. Diffusion Tensor Tractography (DTT)
    2. PaceMaker (FBI with Auto ECG)

13. SUMMARY OF DESIGN CONTROL ACTIVITIES

PS Risk List for software and hardware changes have been is included in this submission. The test methods used are the same as those submitted in the previously cleared submissions (K080038 and K112003). A declaration of conformity with design controls is included in this submission.

14. TRUTHFUL AND ACCURACY CERTIFICATION

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

15. SUBSTANTIAL EQUIVALENCE

Toshiba Medical Systems Corporation believes that the Vantage Titan (model MRT-1504/U4). 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

- IEC60601-1:1988, Amd.1:1991, Amd.2:1995
- IEC60601-1-1:2000
- IEC60601-1-2:2001, Amd.1:2004
- IEC60601-1-4:1996, Amd.1:1999
- IEC60601-1-6:2006
- IEC60601-1-8:2003,Amd.1:2006
- IEC60601-2-33:2002, Amd.1:2005, Amd.2:2007
- IEC60825-1: 2007
- IEC62304:2006
- IEC62366:2007
- NEMA MS-1:2008
- NEMA MS-2:2003
- NEMA MS-3:2008
- NEMA MS-4:2006
- NEMA MS-5:2003
- NEMA PS 3.1-18 (2008)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

JUN - 1 2012

Re: K120638
Trade/Device Name: MRT-1504/U4, Vantage Titan
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 25, 2012
Received: April 26, 2012

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K120638

Indications for Use

510(k) Number (if known): _____

Device Name: MRT-1504/U4, Vantage Titan

Indications for Use:

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- Proton density (PD) (also called hydrogen density)
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- 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.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K120638