510(k) SUMMARY AND EFFECTIVENESS

DEC 13 2012

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ESTABLISHMENT REGISTRATION:** 2020563

3. **CONTACT PERSON AND U.S AGENT INFORMATION:**

Contact Person:	Charlemagne Chua (714) 730-5000
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:** August 24, 2012 (Revised 11-5-2012)

6. **DEVICE NAME:**

Generic Name:	Magnetic Resonance Diagnostic Device
Model Name:	MRT-1504/U5
Trade/ Proprietary Name:	Vantage Titan with Helios gradient

7. **CLASSIFICATION AND CLASS OF DEVICE**

   90-LNH, Class II per 21 CFR 892.1000

8. PREDICATE DEVICE(S):

a. K120638: Vantage Titan, MRT-1504/U4
b. K112003: Vantage Titan HSR, MRT-1504/A5

9. REASON FOR SUMBISSION

Modification of a cleared device

10. Submission Type

Traditional 510(k)

11. DEVICE DESCRIPTION

The Vantage Titan with Helios gradient (Model MRT-1504/U5) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Titan with Helios gradient uses the same magnet as the Vantage Titan (K120638). The gradient performance was modified using the same gradient amplifier and gradient coil as Vantage Titan HSR (K112003).

12. 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 from the previous submission, K120638

13. SUMMARY OF MAJOR HARDWARE CHANGES

a. Gradient Amplifier
b. Gradient Coil

14. SUMMARY OF MAJOR SOFTWARE CHANGES

a. There are no software changes.

15. SUMMARY OF IMPROVEMENTS

a. MRS Scan
b. Altibase (Database SW), version upgrade
c. Scan parameter window
d. Reconstruction speed
e. Locator window operation
f. Clinical application operability
g. Autoview GUI
h. Automatic map-scan
i. Implementation of 3D Advanced Fourier Imaging (AFI)
j. New coils (cardiac, Head, Spine and Flexible SPEEDER)

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16. SAFETY PARAMETERS

	Vantage Titan with Helios gradient (Subject device)	Vantage Titan (K120638)	Vantage Titan HSR (K112003)
a. Static field strength:	1.5T	1.5T	1.5T
b. Peak and A-weighted acoustic noise:	112.0 dB (A-weighed) 122.9 dB(peak)	106.2 dB (A-weighted) 115.4 dB (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
g. Biocompatibility of materials	Confirmed for electrodes and accessories for wireless gating	Confirmed for electrodes and accessories for wireless gating	Confirmed for electrodes and accessories for wireless gating

16. IMAGING PERFORMACE PARAMETERS

No change from the previous predicate submission (K120638).

17. DESIGN CHANGE

The Vantage Titan with Helios gradient MRI System is comparable to the existing 1.5T Vantage Titan MRI System (K120638), with the following modifications.

a. Maximum gradient slew rate have been changed.
b. Maximum gradient strength has been changed.

18. 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 (K120638). A declaration of conformity with design controls is included in this submission.

19. TRUTHFUL AND ACCURACY CERTIFICATION

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

20. SUBSTANTIAL EQUIVALENCE

Toshiba Medical Systems Corporation believes that the Vantage Titan with Helios gradient (model MRT-1504/U5). 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)

21. TESTING

Image Quality metrics utilizing phantoms are provided in this submission. Additionally, testing of the modified system was conducted in accordance with the applicable standards published by the International Electromechanical Commission (IEC) for Medical Devices.

22. CONCLUSION

The modifications incorporated into Vantage Titan with Helios Gradient (MRT-1504/U5), SW V2.20, do not affect the indications for use or the intended use of the device. Safety and effectiveness have been verified via risk management and application of design controls to the modifications,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 13, 2012

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

Re: K122613
Trade/Device Name: Vantage Titan, MRT-1504/U5
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 5, 2012
Received: November 6, 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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
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): K122613

Device Name: Vantage Titan, MRT-1504/U5

Indications for 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:

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- 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.

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)

Janine M. Morris -S
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(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K122613