510(k) SUMMARY

1. **DEVICE NAME:** Magnetic Resonance Diagnostic Device Accessory
   Model Name: MRT-1504/S3
   Trade/Proprietary Name: Vantage Titan

JAN 22 2008

2. **ESTABLISHMENT REGISTRATION:** 2020563

3. **U.S. Agent Name and Address:** Toshiba America Medical Systems, Inc.
   2441 Michelle Drive
   Tustin, Ca 92780

   Contact Person: Paul Biggins
   (714) 730 - 5000

4. **Manufacturing Site:** TOSHIBA CORPORATION
   MEDICAL SYSTEMS COMPANY
   1385 Shimoishigami
   Otawara-shi, Tochigi 324-8550, Japan

5. **DATE OF SUBMISSION:** December 19, 2007

6. **DEVICE DESCRIPTION**

The Vantage Titan (Model MRT 1504/S3) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Titan uses the same magnet as the other Vantage MRI Systems. It includes the Toshiba Pianissimo™ technology (scan noise reduction technology), and has a 1.4 m short magnet. The design of the gradient coil and the WB coil of the Vantage Titan provides the maximum field of view of 55 x 55 x 50 cm.

The Vantage Titan MRI System is comparable to the current EXCELART Vantage Atlas-X MRI System (K063361), cleared November 21, 2006 with the following modifications.

- Gantry bore diameter has been increased from 600mm to 690mm at bore center.
- Maximum power of RF amplifier has been increased from 20KW to 35KW.
- RF amplifier cabinet has been added.
- Gradient power supply has been modified to increase the output current from 300A to 550A.
- Transformer cabinet has been modified to cover the system power requirement.

6.1. SUMMARY OF MAJOR HARDWARE CHANGES

a. Gradient coil has been modified to increased the inside diameter.

b. WB coil has been modified to increased the inside diameter.

c. Maximum power of RF amplifier has been increased from 20KW to 35KW.

d. RF amplifier cabinet has been added.

e. Gradient power supply has been modified to increase the output current from 300A to 550A.

f. Transformer cabinet has been modified to cover the system power requirement.

6.2. SUMMARY OF MAJOR SOFTWARE CHANGES

a. New RF amplifier cabinet control.

b. New gradient power supply control.

c. Add the over temperature protection inside the gantry bore.

d. Modified the data base for distortion correction for new gradient coil.

e. Modified the data base for SAR control for new WB coil.

7. SAFETY PARAMETERS

	Current EXCELART Vantage Atlas-X (No changes from the previous submission, K063361)	**New Vantage Titan**
a. Static field strength:	1.5 T	Same
b. Peak and A-weighted acoustic noise:	110 dB (A-weighted)	Same
c. Operational modes:	1st operating mode for dB/dt and SAR	Same
i. Safety parameter display:	SAR, dB/dt	Same
ii. Operating mode access requirements:	Allows access to 1st level operating mode	Same
d. Maximum SAR	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33 (2002))	Same
f. Maximum dB/dt	<1st operating mode specified in IEC 60601-2-33 (2002)	Same
and Gradient coil dimensions:	692 x 893 x 1405 (unit: mm)	760 x 893 x 1405 (unit: mm)
f. Potential emergency conditions and means provided for shutdown:	Shut down by Emergency Ramp Down Unit for collision hazard by ferromagnetic objects	Same
g. Biocompatibility of materials:	Not applicable	Same

K080038
pg. 3 of 3

8. IMAGING PERFORMANCE PARAMETERS

No changes from the previous submission, K063361.

9. INTENDED USE

No changes from the previous submission, K063361.

10. EQUIVALENCY INFORMATION

Toshiba Medical Systems Corporation believes that the new Vantage Titan (model MRT-1504/S3) Magnetic Resonance Imaging (MRI) system is substantially equivalent to the current EXCELART Vantage Atlas-X (model MRT-1503/S3) (K063361) cleared on November 21, 2006.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2008

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K080038
Trade/Device Name: Vantage Titan
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: January 4, 2008
Received: January 7, 2008

Dear Mr. Job:

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, 1796, 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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080038

Device Name: Vantage Titan

Indications for Use:

Imaging of:

- The Whole Body (including head, abdomen, pelvis, limbs and extremities, spine, neck, TMJ, heart, blood vessels). [Application terms include MRCP (MR Cholangiopancreatography), MR Cisternography, MR Urography, MR Myelography, MR Fluoroscopy, SAS (Surface Anatomy Scan), Dynamic Scan, Cine Imaging and Cardiac tagging.]
- Fluid Visualization
- 2D / 3D Imaging
- MR Angiography / MR Vascular Imaging
- Blood Oxygenation Level Dependent (BOLD) imaging
- Perfusion / Diffusion Imaging
- Proton Spectroscopy

Prescription Use ✓ OR Over-The-Counter Use _____
(Part 21 CFR 801Subpart D) (Part 21 CFR 801Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K080038