510(k) SUMMARY

1. **DEVICE NAME:** Magnetic Resonance Diagnostic Device Accessory
   Model Name: MRT-3010/A5
   Trade/Proprietary Name: Vantage Titan 3T

2. **ESTABLISHMENT REGISTRATION:**

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:** August 30, 2010

6. **DEVICE DESCRIPTION**

The Vantage Titan 3T (Model MRT-3010/A5) is a 3 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Titan 3T uses 1.6m short and 6.4 tons light weight magnet. It includes the Toshiba Pianissimo™ technology (scan noise reduction technology). The design of the gradient coil and the WB coil of the Vantage Titan 3T provides the maximum field of view of 50 x 50 x 45 cm.

The Vantage Titan 3T MRI System is comparable to the current 1.5T EXCELART Vantage Titan MRI System (K080038), cleared January 22, 2008 with the following modifications.

- Field strength of magnet has been changed to 3T.
- RF amplifier, transmitter and receiver (RF cabinet) are modified to adopt the change in resonance frequency (63MHz -> 123MHz).
- Number of RF amplifier channels is increased from 1 to 2.
- Number of receiver channels is 16ch for standard (same as Titan 1.5T), 32ch for optional.
- Software platform has been changed.

NOTE: The Filed Strength Vantage Titan 3T MRI System is equivalent to that of the SIEMENS Verio, which is cleared on October 10, 2007 (K072237).

6.1. SUMMARY OF MAJOR HARDWARE CHANGES

a. Field strength of magnet has been changed to 3T.
b. RF amplifier, transmitter and receiver (RF cabinet) are modified to adopt the change in resonance frequency (63MHz -> 123MHz).
c. Number of RF amplifier channels is increased from 1 to 2.
d. Number of receiver channels is 16ch for standard (same as Titan 1.5T), 32ch for optional.
e. Cooling fan box is separated from filter cabinet.
f. Transformer cabinet has been modified to cover the system power requirement.
g. Wireless gating is added (optional).

6.2. SUMMARY OF MAJOR SOFTWARE CHANGES

a. New RF amplifier cabinet control.
b. New gradient power supply control.
c. New Magnet supervisory control.
d. Modified the data base for SAR control for new WB coil.
e. Modified the data base for distortion correction and dB/dt calculation for new gradient coil.
f. New software platform.

7. SAFETY PARAMETERS

	EXCELART Vantage Titan (K080038)	New Vantage Titan 3T
a. Static field strength:	1.5 T	3T
b. Peak and A-weighted acoustic noise:	105.7dB (A-weighted) 115.7dB (peak)	111.8 dB (A-weighted) 121.3 dB (peak)
c. Operational modes:	1st operating mode	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
e. Maximum dB/dt	<1st operating mode specified in IEC 60601-2-33 (2002)	Same
and Gradient coil dimensions:	760 x 893 x 1405 (inner diameter x outer diameter x length, unit: mm)	749 x 893 x 1405 (inner diameter x outer diameter x length, 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	Confirmed for electrodes and accessories for wireless gating

8. IMAGING PERFORMANCE PARAMETERS

No changes from the previous submission, K080038.

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.

10. EQUIVALENCY INFORMATION

Toshiba Medical Systems Corporation believes that the Vantage Titan 3T (model MRT-3010/A5) Magnetic Resonance Imaging (MRI) System is substantially equivalent to the current Vantage Titan (model MRT-1504/S3) cleared on January 22, 2008 (K080038) except for magnetic field strength (3T instead of 1.5T). Field strength of this system is equivalent to that of SIEMENS Verio, which is cleared on October 10, 2007 (K072237).

Testing was done in accordance with applicable recognized consensus standards as listed below. Additionally, volunteer studies were conducted to verify imaging performance.

IEC 60601-1-1
IEC 60601-1-2
IEC 60601-2-33(2002) + Amd.1 (2005) + Amd.2 (2007)
NEMA MS1, MS2, MS3, MS4, MS5
ACR/NEMA DICOM 3.0

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

AUG - 2 2011

Re: K102489
Trade/Device Name: Vantage Titan 3T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH and MOS
Dated: April 8, 2011
Received: April 18, 2011

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K102489

Indications for Use

510(k) Number (if known): _____

Device Name: Vantage Titan 3T

Indications for Use:

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Prescription Use_____ (Part 21 CFR 801Subpart D) OR Over-The-Counter Use_____ (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)

Mary S Pastel

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

510K K102489