K132160

510(k) SUMMARY AND EFFECTIVENESS

1. CLASSIFICATION and DEVICE NAME:

Classification Name:	**Magnetic Resonance Diagnostic Device**
Regulation Number:	**21 CFR 892.1000**
Product Code:	**LNH**
Trade Proprietary Name:	**Vantage Titan 3T**
Model Number:	**MRT-3010/A5**

2. ESTABLISHMENT REGISTRATION: 2020563

3. CONTACT PERSON, U.S AGENT and ADDRESS:

Contact Person
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Manager, Regulatory Affairs
(714) 669-7896

OCT 16 2013

U.S. Agent Name:
Paul Biggins
Director, Regulatory Affairs
(714) 730-5000

Establishment Name and Address:
Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, Ca. 92780

4. MANUFACTURING SITE:

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

5. DATE OF SUBMISSION:

July 10, 2013

6. DEVICE DESCRIPTION:

The Vantage Titan 3T (Model MRT-3010/A5) is a 3 Tesla Magnetic Resonance Imaging (MRI) System and was cleared under K120487. This submission will include the following

five software functionalities: Changes in the SAR calculation method, 3D ASL (3 dimensional Arterial Spin Labeling), Advanced Moving Bed (AMB), 3D MRS (3 dimensional MR Spectroscopy) and Distortion correction for entire volume are added to Vantage Titan 3T.

7. SUMMARY OF HARDWARE CHANGES

There are no major hardware changes associated with the software change.

8. SUMMARY OF SOFTWARE CHANGES

Existing software packages are grouped by functions of software and pulse sequences. New software (V2.30) packages (four software functionalities) as follows:

a) Changes in the SAR calculation method
The new calculation method provides more flexibility in setting scan parameters, which enables scan with increased number of slices per unit time etc.

b) 3D ASL (3 dimensional Arterial Spin Labeling)
This function of software adds a new feature for current ASL imaging so that images can be acquired from 3D volume instead of 2D slice.

c) Advanced Moving Bed (AMB)
AMB enables individual scan settings for each station when Moving Bed is used. It allows acquisition of images with the most appropriate settings for each station.

d) 3D MRS (3 dimensional MR Spectroscopy)
This function of software enables the acquisition of proton spectroscopic data from multiple voxel in a 3 dimensional volume of an object by applying phase encode gradients in three orthogonal directions.

e) Distortion correction for entire volume
This function of software performs correction of image distortion due to gradient magnetic field non-linearity for entire 3D volume including slice direction.

9. SAFETY PARAMETERS

Item	Vantage Titan 3T with new application software package (subject device)	Vantage Titan 3T , K120487 (Predicate Device)	Notes
Static field strength	3T	3T	Same
Operational Modes	1st Operating Mode	1st Operating Mode	Same

i. Safety parameter display	SAR dB/dt	SAR dB/dt	Same
ii. Operating mode access requirements	Allows screen access to 1st level operating mode	Allows screen access to 1st level operating mode	Same
Maximum SAR	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33(2010))	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33(2002))	Change*
Maximum dB/dt	<1st operating mode specified in IEC 60601-2-33 (2010)	<1st operating mode specified in IEC 60601-2-33 (2002)	Change*
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

***Note:** The difference between predicate and subject device is due to the conformance of the subject device to IEC 60601-2-33 (2010)

10. IMAGING PERFORMACE PARAMETERS

No change from the previous predicate submission (K120487).

11. INTEDED 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 (K120487).

12. DESIGN CHANGE

Following software package addition to Vantage Titan 3T (K120487).

a) Changes in the SAR calculation method
b) 3D ASL (3 dimensional Arterial Spin Labeling)
c) Advanced Moving Bed (AMB)
d) 3D MRS (3 dimensional MR Spectroscopy)
e) Distortion correction for entire volume

13. 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 (K120487).

14. 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.

15. SUBSTANTIAL EQUIVALENCE

Toshiba Medical Systems Corporation believes that the Vantage Titan 3T (model MRT-3010/A5) 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 16, 2013

TOSHIBA MEDICAL SYSTEMS CORPORATION
% Mr. PAUL BIGGINS
DIRECTOR REGULATORY AFFAIRS
2441 MICHELLE DRIVE
TUSTIN CA 92780

Re: K132160
Trade/Device Name: Vantage Titan 3T, MRT-3010/A5 v2.30
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: September 6, 2013
Received: September 9, 2013

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 contact 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. 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,

Michael D. O'Hara for

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): K132160

Device Name: Vantage Titan 3T, v2.30 (MRT-3010/A5)

Indications for 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:

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Michael D. O'Hara