Appendix 1

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **DEVICE NAME:** Magnetic Resonance Diagnostic Device Accessory
   Model Name: MRT-1503/P3, P2
   Trade/Proprietary Name: EXCELART Vantage™ XGV/AGV

2. **ESTABLISHMENT REGISTRATION:** 2020563

3. **U.S. Agent Name and Address:** TOSHIBA AMERICA MEDICAL SYSTEMS,INC.
   2441 MICHELLE DRIVE
   TUSTIN, CA 92780

   Contact Person: Michaela Mahl
   (714) 730 - 5000

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

5. **DATE OF SUBMISSION:** July 11, 2003

6. **DEVICE DESCRIPTION**

The EXCELART Vantage™ XGV/AGV system has the following features compared to the current EXCELART™ with Pianissimo XG/AG SPIN Edition system.

- New gantry design as Ultra-short bore.
- New patient couch design as wide couch top.
- It is possible to combine detachable couch top and gurney of exclusive use.
- The CPU of computer system was changed from RISC type to Xeon.
- dB/dt enabled use by 1st operating mode specified in IEC 60601-2-33(2002) by some sequences.
- SAR enabled use by normal operating mode specified in IEC 60601-2-33(2002).
- The marginal performance (Min.TR/Min.TE / Min.Slice thickness / Imaging area) of a sequence has been improved.
- The gating waveform can be displayed by the side of the gantry.

Model Number with suffix	Trade/Proprietary Name
MRT-1503/P3	EXCELART Vantage™ XGV
MRT-1503/P2	EXCELART Vantage™ AGV

6.1. SUMMARY OF MAJOR HARDWARE CHANGES

A. The magnet system was changed to short bore.

B. The gradient coil was changed to short bore.

C: The patient couch was changed to wide and detachable couch top.

D. It is possible to combine detachable couch top and gurney of exclusive use.

E. The whole body coil was modified for corresponds to SAR 2.0w/kg

F. 4ch flex body array coil is added in the optional items.

G. QD head SPEEDER (K022582) is added in the optional items.

H. The gating waveform can be displayed by the side of the gantry

6.2. SUMMARY OF MAJOR SOFTWARE CHANGES

A. New CPU correspondence.

B. New RF coils control.

C. dB/dt limitation control.

D. SAR limitation control.

7. SAFETY PARAMETERS

	Current EXCELART™ with Pianissimo XG/AG SPIN Edition (No changes from the previous submission, K023511)	New EXCELART Vantage™ XGV/AGV
a. Static field strength:	1.5 T	Same
b. Peak and A-weighted acoustic noise:	95.4 dB (A-weighted)	110 dB (A-weighted)
c. Operational modes:	1st operating mode for dB/dt	Same
i. Safety parameter display:	SAR, dB/dt	Same
ii. Operating mode access requirements:	Not applicable because used only in normal operating mode	Same
d. Maximum SAR	< 1.5 W/kg	< 2.0 W/kg
e. Maximum dB/dt	46 T/sec	<1st operating mode specified in IEC 60601-2-33 (2002)
and Gradient coil dimensions:	1050 x 1175 x 50 (unit: mm)	692 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

8. **IMAGING PERFORMANCE PARAMETERS**

No changes from the previous submission, K023511 .

9. **INTENDED USE**

No changes from the previous submission, K023511 .

10. **EQUIVAALENCY INFORMATION**

TOSHIBA Corporation Medical Systems Company believes that the new EXCELART Vantage™ XGV/AGV (model MRT-1503/P3, MRT-1503/P2) Magnetic Resonance Imaging (MRI) system is substantially equivalent to the current EXCELART™ with Pianissimo XG/AG SPIN Edition (model MRT-1501/P3, MRT-1501/P2) (K023511) cleared on November 05, 2002 except for new gantry and patient couch, new RF coils and dB/dt, SAR limitation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2003

Toshiba America Medical Systems, Inc.
% Ms. Laura Danielson
Responsible Third Party Official
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K032490
Trade/Device Name: Excelart Vantage™ XGV/AGV
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: August 11, 2003
Received: August 12, 2003

Dear Ms. Danielson:

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 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); 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

510(k) Number (if known): K032490

Device Name: EXCELART Vantage™ XGV/AGV

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032490