K02 3511

NOV 5 2002

Appendix 1

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **DEVICE NAME:** Magnetic Resonance Diagnostic Device Accessory

   Model Name: MRT-1501/P3,P2

   Trade/Proprietary Name: EXCELART™ with Pianissimo XG/AG SPIN Edition

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:** September 27, 2002

6. **DEVICE DESCRIPTION**

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

- Extension of a receiving system is enabled a maximum of 8 ch.
- Use of QD Torso SPEEDER corresponding to Parallel imaging which can shorten scan time is enabled.
- The computer only for reconstruction was carried for high-speed image processing.
- dB/dt enabled use by 1st operating mode specified in IEC 60601-2-33 by the TrueSSFP sequence.
- Max. field strength is changed 25mT/m to 30mT/m.
- The marginal performance (Min.TR/Min.TE / Min.Slice thickness / Imaging area) of a sequence has been improved.
- The user interface of software was changed for the improvement of operativity.
- Gating unit was redesigned to improve the making triggers for sequence.

Model Number with suffix	Trade/Proprietary Name
MRT-1501/P3	EXCELART™ with Pianissimo XG SPIN Edition
MRT-1501/P2	EXCELART™ with Pianissimo AG SPIN Edition

6.1. SUMMARY OF MAJOR HARDWARE CHANGES

A. The computer only for reconstruction was carried for high-speed image processing.

B. Gating unit was redesigned to improve the making triggers for sequence.

C: 8ch phased array kit is added in the optional items.

D. 70mm Circular coil is added in the optional items.

E. QD torso SPEEDER is added in the optional items.

F. QD Neurovascular array coil (K001870) is added in the optional items.

6.2. SUMMARY OF MAJOR SOFTWARE CHANGES

A. Improved user interface.

B. New RF coils control.

C. dB/dt limitation control.

D. True Steady State Free Precession (SSFP) sequence.

E. Parallel imaging.

7. SAFETY PARAMETERS

	Current EXCELART™ with Pianissimo XG/AG (No changes from the previous submission, K002531)	New EXCELART™ with Pianissimo XG/AG SPIN Edition
a. Static field strength:	1.5 T	Same
b. Peak and A-weighted acoustic noise:	95.0 dB(A-weighted)	95.4 dB(A-weighted)
c. Operational modes:	Normal operating mode	1st operating mode for dB/dt
i. Safety parameter display:	SAR	SAR, dB/dt
ii. Operating mode access requirements:	Not applicable because used only in normal operating mode	Same
d. Maximum SAR	< 1.5 W/kg	Same
e. Maximum dB/dt	19.3T/sec	46 T/sec
and Gradient coil dimensions:	1050 x 1175 x 51 (unit: mm)	1050 x 1175 x 50 (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, K002531.

9. INTENDED USE

No changes from the previous submission, K002531.

10. EQUIVAALENCY INFORMATION

TOSHIBA Corporation Medical Systems Company believes that the new EXCELART™ with Pianissimo XG/AG SPIN Edition (model MRT-1501/P3, MRT-1501/P2) Magnetic Resonance Imaging (MRI) system is substantially equivalent to the current EXCELART™ with Pianissimo XG/AG (model MRT-1501/P3, MRT-1501/P2) (K002531) cleared on October 26, 2000 except for new RF coils and dB/dt limitation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 5 2002

Toshiba America
Medical Systems, Inc.
% Mr. Mark Job
510(k) Program Manager
TÜV America, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112

Re: K023511
Trade/Device Name: EXCELART™ with Pianissimo XG, AG SPIN Edition
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: October 17, 2002
Received: October 21, 2002

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, 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 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 this 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" (21 CFR Part 807.97). 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): K02 3511

Device Name: EXCELART™ with Pianissimo XG, AG SPIN Edition

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.] {K002531}
- Fluid Visualization {K002531}
- 2D / 3D Imaging {K002531}
- MR Angiography / MR Vascular Imaging {K002531}
- Blood Oxygenation Level Dependent (BOLD) imaging {K002531}
- Perfusion / Diffusion Imaging {K993803, K002531}
- Proton Spectroscopy {K010129}

(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)

David G. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023511