FEB 4 2000

K993803

510(k) Premarket Notification

SUMMARY OF SAFETY AND EFFECTIVENESS

1. **DEVICE NAME:** Magnetic Resonance Diagnostic Device Accessory
   Model Number: MRT-1500 /P2
   Trade/Proprietary Name: EXCELART™ with Pianissimo

2. **ESTABLISHMENT REGISTRATION:** 2636923

3. **U.S. AGENT NAME AND ADDRESS:** Toshiba America MRI, Inc.
   280 Utah Avenue
   South San Francisco, CA 94080

   CONTACT PERSON: Ken Nehmer
   (650)872-2722 ext. 6083

4. **MANUFACTURING SITE:** Toshiba Corporation
   1385 Shimoisigami
   Otawara-shi, Tochigi-Ken
   Japan 324

5. **DATE OF SUBMISSION:** November 8, 1999

6. **DEVICE DESCRIPTION:** This submission consists of a new Magnetic Resonance Imaging system which is based primarily on the cleared EXCELART™ (K990620) with the following new functions added to the standard system.
   - Pianissimo: Gradient acoustic reduction system
   - QD Whole Body coil
   - QD Head coil
   - QD C/T/L Spine Array coil
   - 18.1" LCD flat screen monitor
   - Increase of SAR limit from <1.0 Watts/Kg to < 1.5 Watts/Kg

   The following optional features are introduced in this submission.
   - Flexible Body Array coil
   - Shoulder Array coil
   - Storage Plus Package which includes:
     * 8 GByte hard disk drive
     * memory increase of 256 MBytes
   - EPI Plus Package (see Appendix 15) which includes:
     * extending Diffusion function
     * adding Perfusion function
   - Super FASE Plus Package (see Appendix 19) which includes:
     * ECG - Preparation
     * Fresh Blood Imaging (FBI)
     * Swap Phase Encode Extended Data acquisition (SPEED)
     * Composite MIP

- MRA Plus Package (see Appendix 23) which includes:
  * Visual Preparation
  * Moving Bed
  * 3D Centric scan
  * Sequential Target MIP Display (STAMD)

7. SAFETY PARAMETERS:

	EXCELART™	EXCELART™ w/Pianissimo
Maximum static field strength:	1.5T	1.5T
Rate of change of magnetic field:	19.5 T/sec.	19.35 T/sec.
Maximum radio frequency power	<1.0 W/kg	<1.5 W/kg
Acoustic noise levels (maximum):	110.8 dB	86.0 dB

Acoustic noise data was measured in accordance with NEMA guidelines.

8. IMAGING PERFORMANCE PARAMETERS:

		EXCELART™
Specification volume:	Head:	16cm dsv*
	Body:	28cm dsv*

* Same as previously cleared with initial EXCELART™ system (K990620).

9. INTENDED USE

Anatomical regions:	Head, abdomen, breast, heart, pelvis, joints, neck, TMJ, spine, blood vessels, limbs, and extremities
Nuclei excited:	Hydrogen
Diagnostic use:	Diagnostic imaging of the whole body (including head, abdomen, breast, heart, pelvis, joints, neck, TMJ, spine, blood vessels, limbs, and extremities), fluid visualization, 2D and 3D imaging, MR angiography/MR Vascular Imaging and MR fluoroscopy, Blood Oxygenation Level Dependent (BOLD) Imaging, Diffusion Imaging. [Application terms include MRCP (MR Cholangiopancreatography), MR Cisternography, MR Urography, MR Myelography, SAS (Surface Anatomy Scan), Dynamic Scan, Cine Imaging, and Cardiac Tagging.]

10. EQUIVALENCY INFORMATION:

Toshiba America MRI, Inc. (TAMI), believes that the EXCELART™ with Pianissimo Magnetic Resonance Imaging (MRI) system is substantially equivalent to the EXCELART™ Magnetic Resonance System (K990620) cleared on May 14, 1999.

The new coils introduced are substantially equivalent to existing cleared RF coils as compared in the following table:

New coil	Substantially equivalent to:
EXCELART™ QD Whole Body	MRT-150A QD Whole Body (K922798)
EXCELART™ C/T/L Spine Array	VISART QD Spine Array (K965068)
EXCELART™ QD Head	VISART QD Head (K961092)
EXCELART™ Flex Body	VISART GP Flex (K965068)
EXCELART™ Shoulder Array	MRT-150A Shoulder (K942609)

The optional software packages (EPI Plus, SuperFASE Plus, MRA Plus) used for the EXCELART™ MRI system are based on the same software that was previously cleared as V4 (K983110).

The VISART/Ex MRI system (more powerful gradient system) described in the common Operation Manual located in Appendix 27 (pages S-4 and 6-41 through 6-45) is not part of this submission and will not be made available for sale in the United States of America.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

Ken Nehmer
Manager Regulatory Affairs/Quality Systems
Toshiba America MRI, Inc.
280 Utah Avenue
South San Francisco, CA 94080

Re: K993803
Pianissimo and Other Options for
Excelart MRI System
Dated: November 8, 1999
Received: November 9, 1999
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Nehmer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993803

Device Name: EXCELART™ with Pianissimo and options

Indications for Use:

Imaging of:

The Whole Body (including head, abdomen, breast, heart, pelvis, joints, neck, TMJ, spine, blood vessels, limbs and extremities). [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

Diffusion Imaging

The EPI Plus optional package adds the following to the above indications:

Perfusion Imaging

(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, ENT, and Radiological Devices
510(k) Number K993803