9/25/98

K983110

510(k) Premarket Notification

SUMMARY OF SAFETY AND EFFECTIVENESS

1. **DEVICE NAME:** Magnetic Resonance Diagnostic Device Accessory
   Model Number: MRT-50GP /E2 (FLEXART™), /H2 (FLEXART™/Hyper)
   MRT-150 /F1 (VISART™), /F2 (VISART™/Hyper)

   Trade/Proprietary Name: FLEXART™, FLEXART™/Hyper, VISART™, VISART™/Hyper

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:** September 1, 1998

6. **DEVICE DESCRIPTION:** This submission consists of a software upgrade to the MRT-50GP/E2 (FLEXART™), MRT-50GP/H2 (FLEXART™/Hyper), MRT-150/F1 (VISART™), MRT-150/F2 (VISART™/Hyper)

7. **SAFETY PARAMETERS:**

		V3.5 s/w	V4.0 s/w
Maximum static field strength:	FLEXART™ & FLEXART™/Hyper	0.5 T	0.5 T
	VISART™ & VISART™/Hyper	1.5T	1.5T
Rate of change of magnetic field:	FLEXART™	11 T/sec.	11 T/sec.
	FLEXART™/Hyper	13.3 T/sec.	13.3 T/sec.
	VISART™	13.3 T/sec.	13.3 T/sec.
	VISART™/Hyper	19.5 T/sec.	19.5 T/sec.

		V3.5 s/w	V4.0 s/w
Maximum radio frequency power deposition (SAR):	FLEXART™ & FLEXART™/Hyper	<0.4 W/kg	<0.4 W/kg
	VISART™ & VISART™/Hyper	<1.0 W/kg	<1.0 W/kg
Acoustic noise levels (maximum):	FLEXART™	100.2 dB(A)	100.2 dB(A)
	FLEXART™/Hyper	98.5 dB(A)	98.5 dB(A)
	VISART™	105.3 dB	105.3 dB
	VISART™/Hyper	105.1 dB	105.1 dB

Acoustic noise data was measured in accordance with NEMA guidelines. The user is cautioned to have the patient wear acoustic noise protection during scanning.

8. IMAGING PERFORMANCE PARAMETERS:

		V3.5 s/w	V4.0 s/w
Specification volume: Head:	FLEXART™ & VISART™ †	16cm dsv	16cm dsv
Body:	FLEXART™ & VISART™ †	28cm dsv	28cm dsv

† = specifications for both standard and hyper versions

Sample clinical images are presented for new sequences.

9. INTENDED USE

Anatomical regions: Head, body, extremity, spine, neck, TMJ, and heart
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. [Application terms include MRCP (MR Cholangiopancreatography), 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 Version 4.0 software upgrade for the FLEXART™ and VISART™ systems is substantially equivalent to the software version 3.5 for FLEXART™ (K970573) which was cleared on 7/21/97 and VISART™ (K965068) which was cleared on 7/15/97. TAMI believes that the introduction of cardiac tagging in V4.0 is substantially equivalent to Cardiac Tagging Techniques (K973799) which was cleared on 1/2/98, and CINE Imaging which was cleared with version 3.1 for FLEXART™ (K962138) on 12/23/96. The modifications added to the Version 4.0 software do not raise new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 1999

Ken Nehmer
Quality Engineer
Toshiba America MRI, Inc.
280 Utah Avenue
South San Francisco, CA 94080

Re: K983110
Software Version 4.0 for Flexart and Visart
Dated: December 17, 1998
Received: December 21, 1998
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): K983110

Device Name: **Version 4.0 Software Upgrade (FLEXART™ & VISART™)**

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 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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983110

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

(Optional Format 1-2-96)