

K970573



TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 MICHELLE DRIVE, P.O. BOX 2068,
TUSTIN, CA 92781
PHONE: (714) 730-5000

510(k) Summary

JUL 21 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

- 1. Model Name: MRT-50GP/E2 and MRT-50GP/H2
Device Name: Magnetic Resonance Device
Trade/Proprietary Name: FLEXART™/FLEXART™/Hyper V3.5
- 2. Establishment Registration: 2936923
- 3. U.S. Agent Name and Address: TOSHIBA AMERICA MRI, INC.
280 Utah Ave.
South San Francisco, CA 94080

Contact Person: Steven M. Kay
(714) 730-5000

- 4. Manufacturing Site: Toshiba Corporation
1385 Shimoishigami
Otawara-shi, Tochigi-Ken
Japan 324

- 5. DATE OF SUBMISSION: February 12, 1997

6. DEVICE DESCRIPTION

This submission consists of two upgrades to the MRT-50GP/E2 (FLEXART™) and MRT-50GP/H2 (FLEXART™/Hyper) system. The first is the V3.5 software, which is an upgrade over the V3.1 software. The second is the introduction of phased array coils into the coil lineup. More detailed descriptions appear below.

7. SAFETY PARAMETERS [():FLEXART™/Hyper]

	V3.1	V3.5
Maximum static field strength:	1.5T	Same
Rate of change of magnetic field ($\tau = 1000\text{ms}$):	11 (13.3)T/sec,	11 (13.3)T/sec.
Max. Radio frequency power deposition:	<0.34W/kg	<0.4W/kg
Acoustic Noise levels:	100.2 (98.5) dB	100.2 (98.5) dB
	Maximum	Maximum

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

	V3.1	V3.5
Specification volume: Head:	10 cm dsv	16cm dsv
Body:	20 cm dsv	28cm dsv

Sample phantom images and clinical images were presented for new sequences and optional coils, demonstrating conformance with consensus standards requirements for Signal-to-Noise ratio, Uniformity, Slice Profiles, Geometric Distortion and Slice Thickness/Interslice Spacing.

9. INTENDED USE

Anatomical Region: Head, Body, Extremity, Spine, Neck, TMJ, and Heart

Nuclei excited: Hydrogen

Diagnostic Use: Imaging of the whole body (including the head, abdomen, heart, pelvis, spine, blood vessels, limbs and extremities), fluid visualization, 2D/3D Imaging, MR Angiography, MR. Fluoroscopy

10. Equivalency Information

Toshiba America MRI, Inc. (TAMI) believes the FLEXART™ V3.5 software is substantially equivalent to the FLEXART™ V3.1 software because it consists of software upgrades that improve the image quality and performance of the FLEXART™, without introducing new questions of safety or efficacy. The FLEXART™ V3.1 was cleared by K962138. Although the new coils expand the indications for use, they do not change the intended use of the FLEXART™ system. Good Manufacturing Practices requirements are unchanged from those already in effect for V3.1 and the FLEXART™.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Steven M. Kay
Regulatory Affairs Specialist
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
P.O. Box 2068
Tustin, CA 92681-2068

Re: K970573
FLEXART™/FLEXART™/Hyper V3.5
Software
Dated: February 12, 1997
Received: February 14, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

JUL 21 1997

Dear Mr. Kay:

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 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 requirement, 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/dsmamain.htm>!

Sincerely yours,

Lillian Yin, Ph.D.
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): K 970573

Device Name: Flexart™ (MRT-50GP) Version 3.5 Software

Indications for Use:

Imaging of:

- The Whole Body (including head, abdomen, pelvis, limbs and extremities, joints, spine, neck, TMJ, heart, blood vessels, and breast). [Application terms include MRCP (MR Cholangiopancreatography), MR Urography, MR Myelography, SAS (Surface Anatomy Scan), Dynamic Scan and Cine Imaging.]
- Fluid Visualization
- 2D/3D Imaging
- MR Angiography/MR Vascular Imaging

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Edward A. Rejnman
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K970573

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use