K965068

JUL 15 1997

510(k) Summary

SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Model Name:** MRT-150/H1 and MRT-150/F1
   MRT-150/H2 and MRT-150/F2

   Device Name: Magnetic Resonance Device

   Trade/Proprietary Name: VISART™ and VISART™/Hyper

2. **Establishment Registration:** #2020563

3. **U.S. Agent Name and Address:** TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
   2441 Michelle Drive
   P.O. Box 2068
   Tustin, CA 92681-2068

   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:** 16 December 1996

6. **DEVICE DESCRIPTION**

   This submission consists of three upgrades to the MRT-150/H1 and MRT-150/F1 (VISART™) system. The first upgrades the software from V3.1 (which was the software cleared with the VISART™ in K961092) to V3.5. The second is the introduction of the VISART™/Hyper system, which increases the gradient field strength over that of the standard VISART™ with V3.5 software. The third is the introduction of optional phased array coils.

7. SAFETY PARAMETERS

	VISART™ V3.1	VISART™ V3.5	VISART™/Hyper V3.5
Maximum static field strength:	1.5T	Same	Same
Rate of change of magnetic field (τ = 1000ms):	13.3T/sec,	13.3T/sec.	19.5T/sec.
Max. Radio frequency power deposition:	<1.0W/kg	<1.0W/kg	<1.0W/kg
Acoustic Noise levels: (Maximum)	105.3 dB (Maximum)	105.3 dB (Maximum)	105.1 dB

Acoustic noise data was measured in accordance with NEMA guidelines. In the labeling, the user is cautioned to have the patient wear acoustic noise protection during scanning. The VISART™/Hyper system includes additional noise absorption foam inside.

8. IMAGING PERFORMANCE PARAMETERS

		VISART™ V3.1	VISART™ V3.5	VISART™/Hyper V3.5
Specification volume:	Head:	10 cm dsv	16cm dsv	16cm dsv
	Body:	20 cm dsv	28cm dsv	28cm dsv

Sample phantom images and clinical images were presented for all new sequences, 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 Medical Systems, Inc. (TAMS) believes that the VISART™ V3.5 software is substantially equivalent to the VISART™ V3.1 software because it consists of upgrades that improve the performance of the VISART™, without introducing new questions of safety or efficacy. The increased rate of change of the magnetic field is less than the Agency's acceptance limit of 20 T and that of other manufacturers systems currently on the market. This software upgrade provides improved image quality, but does not change the intended uses of the device. Good Manufacturing Practices requirements are unchanged from those already in effect for V3.1 and the VISART™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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: K965068
Software Version 3.5 and Hardware Upgrades
For VISART
Dated: April 15, 1997
Received: April 16, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

JUL 15 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.html".

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): _____

Device Name: **VISART™ Version 3.5 Software**

Indications for Use:

Imaging of:

- The Whole Body (including head, abdomen, pelvis, limbs and extremities, spine, neck, TMJ, heart, blood vessels and breast). [Application terms include MR Fluoroscopy, MR Urography, MRCP (MR Cholangiopancreatography), 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)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K965068

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

(Optional Format 1-2-96)