

K961092

JUN 14 1996

# 510(k) Summary

## SUMMARY OF SAFETY AND EFFECTIVENESS

- 1. **Model Name:** MRT-150A/H1 and MRT-150A/F1  
**Device Name:** Magnetic Resonance Device  
**Trade/Proprietary Name:** VISART™
- 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:** March ? 1996

### 6. DEVICE DESCRIPTION

The VISART™ consists of two model upgrades to the MRT-150A system which provide increased gradient field strength, more ergonomic computer architecture, improved scan parameter specifications and a lighter magnet than the MRT-150A.

### 7. SAFETY PARAMETERS

	<u>MRT-150A</u>	<u>MRT-150/H1</u>	<u>MRT-150/F1</u>
Maximum static field strength:	1.5T	Same	Same
Rate of change of magnetic field ( $\tau = 1000\text{ms}$ ):	7.5T/sec.	13.3T/sec.	13.3T/sec.
Max. Radio frequency power deposition:	<1.0W/kg	<0.4W/kg	<0.4W/kg
Acoustic Noise levels:	85 - 100 dB (Typical)	105.3 dB (Maximum)	103.9 dB (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.

# 510(k) Summary (cont'd)

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### 8. IMAGING PERFORMANCE PARAMETERS

		<u>MRT-150A</u>	<u>MRT-150/H1</u>	<u>MRT-150/F1</u>
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 the VISART™ is substantially equivalent to the MRT-150A because it consists of hardware and software upgrades that improve the performance of the MRT-150A, without introducing new questions of safety or efficacy. The MRT-150A was cleared by K903768A. The improved computer system architecture and user interface were cleared with the Flexart™ via K933018. The increased gradient field strength is less than the IEC standard and that of other manufacturers systems currently on the market. New surface coils for this system received prior market clearance from the Agency. The new magnet offers siting and shipping advantages, but does not change the system's performance characteristics. Software upgrades provide for improved image quality, but do not change the intended uses of the device. MR Fluoroscopy is similar to the same function that was cleared for the MRT-35A. Good Manufacturing Practices requirements are unchanged from those already in effect for the MRT-150A.