

OCT 25 1996

# 510(k) Summary

K962933

## SUMMARY OF SAFETY AND EFFECTIVENESS

1. **DEVICE NAME:** Magnetic Resonance Device  
**Model Number:** MRT-600  
**Trade/Proprietary Name:** OPART™

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 America MRI, Inc.  
280 Utah Avenue  
South San Francisco, CA 94080

5. **DATE OF SUBMISSION:** July 26, 1996

### 6. DEVICE DESCRIPTION

The OPART™ is a modification of the Flexart™ 0.5T system that employs a 0.35T open architecture vertical field superconducting magnet. The computer architecture, operational characteristics and user software follow the same design considerations cleared with the Flexart™ and Visart™ systems. The vertical magnetic field concept is similar to that developed for the Access™ permanent magnet system but uses the same 0.35T field strength as that employed by the MRT-35A. The patient couch allows both manually controlled left/right and in/out horizontal movements similar to the Access Compass Bed.

### 7. SAFETY PARAMETERS

	<u>OPART</u>	<u>Flexart</u>	<u>Visart</u>
Maximum static field strength:	0.35T	0.5T	1.5T
Rate of change of magnetic field ( $\tau = 1000\text{ms}$ ):	18.5 T/sec	11 T/sec,	13.3T/sec.
Max. Radio frequency power deposition:	<0.244W/kg	<0.256 W/kg	<0.4W/kg
Acoustic Noise levels:	98.4 dB (A) (Maximum)	100.2 dB (A) (Maximum)	105.3 dB (Maximum)

# 510(k) Summary (cont'd)

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### 8. IMAGING PERFORMANCE PARAMETERS

		<u>OPART</u>	<u>Flexart</u>	<u>Visart</u>
Specification volume:	Head:	10cm dsv	10.4cm dsv	16cm dsv
	Body:	20cm dsv	10.4cm 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 MRI, Inc. (TAMI) believes the OPART™ is substantially equivalent to the Flexart™ and Access™ diagnostic magnetic resonance systems because it consists of hardware and software modifications that do not introduce new questions of safety or efficacy, nor does it introduce new indications for use. OPART™ uses a superconducting magnet that has a static magnetic field less than that of the cleared Flexart™ and in the same orientation as the Access™. The 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 are designed to be compatible with the vertical field of the magnet, as compared with the horizontal field of the standard Flexart™ system. Toshiba has prior experience designing vertical field coils for its Access system. The new magnet offers siting, shipping and patient access advantages, but does not change the system's intended use. Good Manufacturing Practices requirements and software development procedures are unchanged from those already in effect for the Flexart™. The patient couch is similar to the cleared Compass Bed.