JAN 1 8 2000

510(k) Premarket Notification

K993574

SUMMARY OF SAFETY AND EFFECTIVENESS

1.	**DEVICE NAME:** **Model Number:** **Trade/Proprietary Name:**	Magnetic Resonance Diagnostic Device Accessory MRT-600 OPART™ including: OPART™/Prodiga, (v3.0 & manual bed) OPART™/Potenza (v3.2 & motorized bed) OPART™/Paragon (v3.3, motorized bed, & array electronics)
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 America MRI, Inc. 280 Utah Avenue South San Francisco, CA 94080
5.	**DATE OF SUBMISSION:**	October 19, 1999
6.	**DEVICE DESCRIPTION:**	Versions v3.0/v3.1/v3.2/v3.3 software are a combination of modifications and the addition of new sequences to the existing software, which facilitate the acquisition and reconstruction of MR images. The four versions have the same base software features with certain additional features available in each subsequent version (see Comparison Table, Appendix B, for detailed description). A brief description follows: v3.0: Based on v2.5 (K990260) with MR Angio and FASE sequences removed v3.1: Based on v2.5 (K990260) v3.2: Based on v2.6 (K990260) v3.3: Based on v2.6 (K990260) with addition of Perfusion/Diffusion imaging A brief summary of the new software functionality is described below:

6.1 DESCRIPTION OF NEW SOFTWARE FUNCTIONALITY (v3.0/v3.1/v3.2/v3.3)

A. Increase in software limit of SAR from <0.4Watt/kg to <1.5Watt/kg

B. Multi-phase/Multi-slice for cardiac gating

C. Peripheral gating (optional) software support

D. Flouro monitor with pointing device (optional) software support

E. Dual-channel RF coil array (optional) software support

Removal of Functionality for v3.0 only

A. Removal of MR Angiography sequences

B. Removal of FASE sequences

Additional Functionality for v3.1, v3.2, & v3.3 only

A. Multi-slice 2D PS MRA

B. Gated Angio support

Additional Functionality for v3.3 only

A. FSE Enhancement-1mm thickness, shorter ΔTE, dual contrast

B. 3 point Dixon FE3D Water/Fat

C. Diffusion imaging

D. Perfusion imaging

OPTIONAL HARDWARE ITEMS

A. Extremity Array coil

B. Fluoro Monitor & Pointing Device

C. Peripheral Pulse Gating

D. Motorized Bed

7. SAFETY PARAMETERS:

Maximum static field strength:	0.35 Tesla
Rate of change of magnetic field:	19T/second
Maximum radio frequency power deposition (SAR):	<1.5 Watt/kg
Acoustic noise levels (maximum):	98.4 dB (A)

8. IMAGING PERFORMANCE PARAMETERS:

Specification volume:	Head:	10cm dsv
	Body:	20cm dsv

Sample phantom images and clinical images are presented for new sequences (see Appendices K & L).

9. INTENDED USE

Anatomical regions:	Head, body, extremity, spine, neck, TMJ, breast, and heart
Nuclei excited:	Hydrogen
Diagnostic use:	Diagnostic imaging of the human body (including head, abdomen, pelvis, limbs and extremities, spine, neck, TMJ, heart, blood vessels). [Application terms include MRCP (MR Cholangiopancreatography), MR Urography, MR Myelography, MR Fluoroscopy, SAS (Surface Anatomy Scan), Dynamic Scan and Cine Imaging.] Fluid Visualization and 2D/3D Imaging. MR angiography/MR Vascular Imaging (v3.1, v3.2, & v3.3 only) Water/Fat imaging (v3.2 & v3.3 only) Perfusion/Diffusion imaging (v3.3 only)

10. **EQUIVALENCY INFORMATION**

Toshiba America MRI, Inc., believes that the versions v3.0/v3.1/v3.2/v3.3 software upgrades for OPART™ system is substantially equivalent to the software which was cleared with versions v2.5/v2.6 (K990260). Data pertaining to the increase in the SAR limit from < 0.4 Watt/kg to <1.5 Watt/kg is discussed in Appendix J. MR Angiography has been removed from the indications for use for v3.0 software only. Versions v3.1, v3.2, and v3.3 software includes MR angiography in their indications for use. Version v3.2 and v3.3 includes Water/Fat imaging to their indications for use which was cleared in v2.1 software (K981475). Version v3.3 adds Diffusion/Perfusion imaging to the indications for use statement and is substantially equivalent to v4.0 software for FLEXART/VISART (K983110). The Extremity Array coil is substantially equivalent to the currently cleared OPART™ Extremity coil (K962933). The Fluoro monitor and pointing device is substantially equivalent to the currently cleared OPART™ Fluoro monitor (K962933). The Peripheral Pulse gating unit is substantially equivalent to the VISART/FLEXART Peripheral Pulse gating described in K983110 and K962138. The Motorized Bed is substantially equivalent to the ACCESS™ Compass Bed (K946244/A1) and the FLEXART Bed (K933018/S1).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratio
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2000

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

RE: K993574
OPART™ (Model MRT-600) including:
OPART™ /Prodiga, OPART™/Potenza
and OPART™/Paragon
Dated: October 18, 1999
Received: October 21, 1999
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH/90 MOS

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): K993574

Device Name: **v3.0/v3.1/v3.2/v3.3 Software and Optional Hardware Upgrade OPART™ (MRT-600)**

Indications for Use:

Imaging of:

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

Additional indications for v3.1, v3.2, & v3.3 (only)
- MR Angiography/MR Vascular Imaging

Additional indication for v3.2 & v3.3 (only)
- Water/Fat Imaging

Additional indication for v3.3 (only)
- Perfusion/Diffusion Imaging

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993574