

APR 75

510(k) Premarket Notification**Summary of Safety and Effectiveness**

- 1. DEVICE NAME:** Magnetic Resonance Diagnostic Device
Accessory
Model Number: MRT - 600
Trade/Proprietary Name: OPART™
- 2. ESTABLISHMENT REGISTRATION:** 293623
- 3. U.S. AGENT Name and Address:** Toshiba America MRI, Inc.
280 Utah Avenue
South San Francisco, CA 94080
- Contact Person:** Bruce Clark
(650) 742-6068
- 4. Manufacturing Site:** Toshiba America MRI, Inc.
280 Utah Avenue
South San Francisco, CA 94080
- 5. Date of Submission:** January 25, 1999
- 6. DEVICE DESCRIPTION:**
Version 2.5/V2.6 software is a combination of modifications and the enhancement of sequences to the existing software, which facilitate the acquisition and reconstruction of MR images. This software will function on both SGI Indigo 2 and O2 computer workstations. The V2.6 software may also be identified as Performance Plus option.
- 7. SAFETY PARAMETERS:**
- | | |
|---|-------------|
| Maximum static field strength: | 0.35 Tesla |
| Rate of change of magnetic field: | 19T/second |
| Maximum radio frequency power deposition (SAR): | <0.4Watt/kg |
| Acoustic noise levels (maximum): | 98.4 dB (A) |
- Note:** These safety parameters remain unchanged from previous submissions.
- 8. IMAGING PERFORMANCE PARAMETERS:**
- | | | |
|-----------------------|-------|----------|
| Specification volume: | Head: | 10cm dsv |
| | Body: | 20cm dsv |

Sample phantom images and clinical images are 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 regions:	Head, body, extremity, spine, neck, TMJ, breast and heart
Nuclei excited:	Hydrogen
Diagnostic use:	Diagnostic imaging of the human body (including head, abdomen, breast, heart, pelvis, spine, blood vessels, limbs, and extremities), fluid visualization, 2D and 3D imaging, MR angiography and MR fluoroscopy.

10. EQUIVALENCY INFORMATION:

Toshiba America MRI, Inc., believes that the OPART™ version 2.5/2.6 software is substantially equivalent to the OPART™ version 2 diagnostic resonance system software accessories in that it consists of modifications that do not raise new questions of safety or efficacy. This software does not introduce any new indications for use from those cleared in the Premarket Notifications for OPART™ version 2 diagnostic resonance systems 510(k) number K981475.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 1999

Bruce Clark
QA Engineer
Toshiba America MRI, Inc.
280 Utah Avenue
South San Francisco, CA 94080

Re: K990260
OPART™ (MRT-600)
Dated: January 25, 1999
Received: January 27, 1999
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Clark:

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):

K99 0260

Indications for Use:

Imaging of:

- The Whole Body (including head, abdomen, breast, 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
- 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)

Perscription Use _____
(Per 21 CFR§801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

CONFIDENTIAL

David L. Symon
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K990260