

K983475

JUL 14 1998

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:** 2636923

3. **U.S. AGENT NAME AND ADDRESS:** Toshiba America MRI, Inc.
280 Utah Avenue
South San Francisco, CA 94080

CONTACT PERSON: Bruce Clark
(650)872-2722 ext. 6068

4. **MANUFACTURING SITE:** Toshiba America MRI, Inc.
280 Utah Avenue
South San Francisco, CA 94080

5. **DATE OF SUBMISSION:** April 20, 1998

6. **DEVICE DESCRIPTION:** Versions 2 (V2) software is a combination of modifications and the addition of new sequences to the existing software, which facilitate the acquisition and reconstruction of MR images.

7. **SAFETY PARAMETERS:**
Maximum static field strength: 0.35 Tesla
Rate of change of magnetic field: 19T/second
Maximum radio frequency power deposition (SAR): <0.4 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.

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 Versions 2 (V2) software upgrade for OPART™ system is substantially equivalent to the software which was cleared with the initial OPART™ system (K962933). The modifications added to the Versions 2 (V2) software 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 Notification for OPART™ diagnostic resonance system 510(k) number K962933.



JUL 14 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Bruce Clark
Toshiba America MRI, Inc.
280 Utah Avenue
South San Francisco, CA 94080Re: K981475
Version 2 Software Upgrade for OPART™ MRI System
Dated: April 23, 1998
Received: April 24, 1998
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 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,

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): K98 1475

Device Name: OPART™ (MRT-600) Versions 2 Software Upgrade

Indications for Use: (unchanged from initial OPART™ system K962933)

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), Dynavic 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)

[Signature]
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K981475

Prescription Use X
(Per 21 CFR§801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)