MAY 20

K991057

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:
   Ken Nehmer
   (650)872-2722 ext. 6083

4. **MANUFACTURING SITE:** same as above

5. **DATE OF SUBMISSION:** March 29, 1999

6. **DEVICE DESCRIPTION:**
   The Extra Large Body coil is an enlarged version of the current OPART™ Large Body Coil. This coil is an optional coil which was developed to allow positioning of larger sized patients in the OPART™ system. The Extra Large Body coil can be used as a standalone coil, or in conjunction with the T-spine surface coil (cleared with OPART™ system K962933). Signal is received in QD mode when used in conjunction with the T-spine surface coil.

   The Extra Large Body Coil is constructed with the same materials that are currently in use for the released coil set for OPART™.

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 from the Extra Large Body coil (Appendix 5 & 6).

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 Extra Large Body Coil option for OPART™ system is substantially equivalent to the current Large Body Coil which was cleared with the OPART™ diagnostic resonance system 510(k) number K962933.

This optional coil does not introduce any new indications for use from those cleared in the Premarket Notification for OPART™ diagnostic resonance system 510(k) number K962933.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1999

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

RE: K991057
Body Coil for OPART (Model MRT-600)
Dated: March 29, 1999
Received: March 30, 1999
Regulatory Class: II
21 CFR 892.1000/Procode: 90 MOS

Dar 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): K991057

Device Name: **Extra Large Body Coil for OPART™ (MRT-600)**

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)

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 K991057

CONFIDENTIAL