K023207

OCT 0 9 2002

Appendix 1

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **DEVICE NAME:** Magnetic Resonance Diagnostic Device Accessory

   Model Name: MRT-600EX

   Trade/Proprietary Name: OPART™

   including OPART™ /Ultra and Ultra gradient system upgrade kit

2. **ESTABLISHMENT REGISTRATION:** 2020563

3. **U.S. Agent Name and Address:** TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
   2441 MICHELLE DRIVE
   TUSTIN, CA 92780

   Contact Person: Michaela Mahl
   (714) 730 - 5000

4. **Manufacturing Site:** TOSHIBA CORPORATION
   MEDICAL SYSTEMS COMPANY
   1385 Shimoishigami
   Otawara-shi, Tochigi 324-8550, Japan

5. **DATE OF SUBMISSION:** August 01, 2002

6. **DEVICE DESCRIPTION**

The OPART™ /Ultra system is added into existing OAPRT™ series by incorporating the high performance gradient system. The OPART™ /Ultra system and the OPART™ system with Ultra gradient upgrade kit offers the modified sequences for the faster acquisition than existing OPART™ systems. The following model number with suffix corresponds to the Trade/Proprietary Name respectively.

Model Number with suffix	Trade/Proprietary Name
MRT-600EX /PR	OPART™
MRT-600EX /UH	OPART™ /Ultra (Manual bed model)
MRT-600EX /U1	OPART™ /Ultra (Motorized bed model)
MZKT-GP0302 /U1	OPART ™ Ultra gradient system upgrade kit

The following five versions have the same base software features with certain additional features available in each subsequent version (see Comparison Table, Appendix 7, for detailed description). A brief description follows:

V4.0: V4.00 onto v3.0 (K993574)

V4.1: V4.00 onto v3.1 (K993574)

V4.2: V4.00 onto v3.2 (K993574)

V4.3: V4.00 onto v3.3 (K993574)

V4.4: Based on v3.3 (K993574) with addition of fast acquisitions. This software is only available for OPART™ /Ultra system.

A brief summary of the changes are described below:

6.1. SUMMARY OF MAJOR HARDWARE CHANGES

A. For the OPART™ /Ultra system, the existing gradient amplifier in the control cabinet is eliminated and the high performance gradient power supply is added as a stand alone cabinet.

B. For the OPART™ /Ultra system, the cooling pipes are integrated into the gradient coils.

C: All the OPART™ standard configuration has only Open TX coil and QD Head coil, and other RF coils are moved to the options.

D. QD/Array Neck coil (K000549) is added in the optional items.

E. QD/Array Shoulder coil (K013854) is added in the optional items.

F. QD C/T/L Array Spine coil (K000002) is added in the optional items.

6.2. SUMMARY OF MAJOR SOFTWARE CHANGES

A. Improved user interface. (for V4.0, V4.1, V4.2, V4.3, V4.4)

B. High performance gradient power supply control (only for V4.4)

C. Single Shot EPI (SS-EPI) (only for V4.4)

D. Advanced Steady State Free Precession (SSFP) (only for V4.4)

E. Super FASE, shorter • TE version of FASE. (only for V4.4)

7. SAFETY PARAMETERS

	OPART™ (No changes from the previous submission, K993574)	OPART™ /Ultra
a. Static field strength:	0.35 T	Same
b. Peak and A-weighted acoustic noise:	108 dB (Peak) 98.4 dB(A-weighted)	115.4 dB (Peak) 102.5 dB(A-weighted)
c. Operational modes:	Normal operating mode	Same
i. Safety parameter display:	SAR	Same
ii. Operating mode access requirements:	Not applicable because used only in normal operating mode	Same
d. Maximum SAR	< 1.5 W/kg	Same
e. Maximum dB/dt	19 T/sec	51 T/sec
and Gradient coil dimensions:	1050 x 1175 x 51 (unit: mm)	1050 x 1175 x 50 (unit: mm)
f. Potential emergency conditions and means provided for shutdown:	Shut down by Emergency Ramp Down Unit for collision hazard by ferromagnetic objects	Same
g. Biocompatibility of materials:	Not applicable	Same

8. IMAGING PERFORMANCE PARAMETERS

No changes from the previous submission, K993574.

9. INTENDED USE

No changes from the previous submission, K993574.

10. EQUIVAALENCY INFORMATION

TOSHIBA Corporation Medical Systems Company believes that the OPART™ /Ultra (model MRT-600EX/UH, MRT-600EX/U1) Magnetic Resonance Imaging (MRI) system or the OPART™ system with Ultra upgrade kit (MZKT-GP0302/U1) is substantially equivalent to the OPART™ (model MRT-600) (K993574) cleared on January 18, 2000 except for Gradient System.

As for the Gradient System on OPART™ /Ultra system, it is substantially equivalent to the Gradient System on EXCELART™ with Pianissimo. The hardware configuration is substantially equivalent to model MRT-1501 /P2 system (K993803) cleared on February 4, 2000 and the gradient performance such as the maximum slew rate and gradient strength is substantially equivalent to model MRT-1501 /P3 system (K002531) cleared on October 26, 2000.

The difference of the gradient performance by using the substantially equivalent hardware with MRT-1501 /P2 is due to the difference of the gradient coil design. The OPART™ /Ultra has the similar gradient performance to MRT-1501 /P3 with the hardware configuration substantially equivalent to MRT-1501 /P2 except for the gradient coil.

TOSHIBA Corporation Medical Systems Company also performed the dB/dt and acoustic noise verifications on OPART™ /Ultra system.

The new Gradient System offers advantages of faster acquisitions, 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 EXCELART™ with Pianissimo.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 9 2002

Toshiba America
Medical Systems, Inc.
% Mr. Mark Job
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K023207
Trade/Device Name: Opart™ (including Opart Ultra and Ultra Gradient Upgrade Kit)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: September 24, 2002
Received: September 25, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023207

Device Name: OPART™ (including OPART™/Ultra and Ultra gradient system upgrade kit)

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
- MR Angiography / MR Vascular Imaging
- Water / Fat Imaging
- 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 ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023207