

510(k) Premarket Notification

SUMMARY OF SAFETY AND EFFECTIVENESS

- | | | | | | | | | | | |
|---|--|--|--------------------------------|----------------|-----------------------------------|----------------|---|--------------|----------------------------------|-------------|
| 1. | DEVICE NAME
Model Number
Trade/Proprietary Name | Magnetic Resonance Diagnostic Device Accessory
MRT-600
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 | May 19, 1999 | | | | | | | | |
| 6. | DEVICE DESCRIPTION | <p>The Flexible Small Parts coil is comprised of a flexible coil winding, tune box, and clamp. The flexible coil winding is fabricated from a single strip of copper and encased in soft closed cell foam. The winding conforms to the irregular surface of anatomy and keeps the shape it is formed to while the foam provides consistent spacing between the windings and anatomy.</p> <p>Decoupling is dual active and achieved with PIN diodes. The impedance of the coil is 50 ohms nominal and it is a solenoid type coil.</p> <p>The Flexible Small Parts coil is constructed with the same materials that are currently in use for the released coil set for OPART™.</p> | | | | | | | | |
| 7. | SAFETY PARAMETERS | <table border="0" style="width: 100%;"> <tr> <td style="width: 60%;">Maximum static field strength:</td> <td style="width: 40%;">0.35 Tesla</td> </tr> <tr> <td>Rate of change of magnetic field:</td> <td>19T/second</td> </tr> <tr> <td>Maximum radio frequency power deposition (SAR):</td> <td><0.4 Watt/kg</td> </tr> <tr> <td>Acoustic noise levels (maximum):</td> <td>98.4 dB (A)</td> </tr> </table> | 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) |
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| 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 | <table border="0" style="width: 100%;"> <tr> <td style="width: 60%;">Specification volume:</td> <td style="width: 40%;">Head: 10cm dsv</td> </tr> <tr> <td></td> <td>Body: 20cm dsv</td> </tr> </table> | Specification volume: | Head: 10cm dsv | | Body: 20cm dsv | | | | |
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Sample phantom images and clinical images are presented from the Extra Large Body coil (Appendix 6 & 7).

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, extremities, and small parts which include: wrist, elbow, ankle, shoulder, hand, knee), fluid visualization, 2D and 3D imaging, MR angiography and MR fluoroscopy.

10. EQUIVALENCY INFORMATION

Toshiba America MRI, Inc., believes that the Flexible Small Parts coil option for OPART™ system is substantially equivalent to the current Small Belt and Extremity coils which were 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.



AUG - 2 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

RE: K991740
OPART™ Model MRT-600 Flexible
Small Parts Coil, MRI Accessory
Dated: May 19, 1999
Received: May 21, 1999
Regulatory Class: II
21 CFR 892.1000/Procode: 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): K991740

Device Name: Flexible Small Parts Coil with OPART™ (MRT-600)

Indications for Use:

Imaging of:

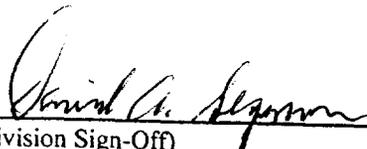
- The Whole Body (including head, abdomen, breast, pelvis, limbs and extremities, spine, neck, TMJ, heart, blood vessels, small parts which include: wrist, elbow, ankle, shoulder, hand, knee). [Application terms include MRCP (MR Cholangiopancreatography), MR Urography, MR Myelography, MR Fluoroscopy, 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 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 K991740