JUL 1 4 2005

K051763

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. DEVICE NAME

Magnetic Resonance Diagnostic Device Accessory

Model Number

MJQJ-147A

Trade/Proprietary Name

QD KNEE/FOOT COIL™

2. ESTABLISHMENT REGISTRATION

2020563

3. U.S. AGENT NAME AND ADDRESS

Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle DriveTustin, CA 92780

CONTACT PERSON

Michaela Mahl
(714) 730-5000

4. MANUFACTURING SITE

Toshiba Medical Systems Corporation (TMSC)
1385, Shimoishigami, Otawara-Shi, Tochigi 324-8550, Japan

5. DATE OF SUBMISSION

June 16, 2005

6. DEVICE DESCRIPTION

The QD KNEE/FOOT COIL is QD volume coil that can transmit RF and receive NMR signal from like the knee or other extremity regions.

The QD KNEE/FOOT COIL is comprised of coil element and PC board. The coil element shapes STIR type coil. The PC board switches transmit mode and receive mode with PIN diodes and combines the NMR signals.

The QD KNEE/FOOT COIL is constructed with the same materials that are currently in use for the released QD KNEE COIL.

7. SAFETY PARAMETERS

Maximum static field strength	1.5 Tesla
Rate of change of magnetic field	30 mT/second
Maximum radio frequency power deposition (SAR)	< 4.8 watt/kg
Acoustic noise levels (maximum)	110 dB(A-weighted)

8. IMAGING PERFORMANCE PARAMETERS

Specification volume	15 cm dsv

Sample phantom images and clinical images are presented in Appendix F & G.

9. INTENDED USE

Anatomical regions	Knee, ankle and foot regions
Nuclei excited	Hydrogen
Diagnostic use	Diagnostic imaging of the human body, fluid visualization, 2D and 3D imaging, MR angiography and MR fluoroscopy

10. EQUIVALENCY INFORMATION

Toshiba Medical Systems Corporation believes that this QD Knee/Foot coil is substantially equivalent to the current QD Knee coil (K032490).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2005

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services
1394 25th Street NW
BUFFALO MN 55313

Re: K051763
Trade/Device Name: QD Knee/Foot Coil for Vantage MRI System (MRT-1503)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: June 28, 2005
Received: June 30, 2005

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 (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 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 Section 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:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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): K051763

Device Name: QD Knee/Foot Coil for Vantage MRI System (MRT-1503)

Indications for Use:

Imaging of:

- Diagnostic imaging of the knee, ankle and foot regions
- Fluid visualization
- 2D and 3D imaging
- MR angiography
- MR fluoroscopy

(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051763