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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 25 2011

1. Applicant

Quality Electrodynamics (QED)
700 Beta Drive, Suite 100
Mayfield Village, OH 44143
Phone (440) 484-2228

2. Contact

Christie Zydyk, MBA
Chief Regulatory Affairs and Quality Assurance Officer

3. Date prepared:

February 25, 2011

4. Tradename

Toshiba 1.5T Extra Large Knee Coil

5. Common name

Coil, magnetic resonance, specialty

6. Classification

21 CFR 892.1000

7. Equivalent Device

Trade name	Legally marketed predicate device	Manufacturer
Toshiba 1.5T Extra Large Knee Coil	1.5T QD Knee Coil	Toshiba Medical Systems Corp.

8. Device Description

The Toshiba 1.5T Extra Large Knee Coil is designed for use with the with the 1.5T EXCELART Vantage and the 1.5T Vantage Titan MR Systems manufactured by Toshiba Medical Systems Corporation.

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9. Intended Use

For use with a Toshiba 1.5T EXCELART Vantage or 1.5T Vantage Titan magnetic resonance scanner to produce diagnostic images of the knee that can be interpreted by a trained physician.

10. Comparison with Predicate Devices

510(k) #	Legally marketed predicate device	Manufacturer
K051763	1.5T QD Knee/Foot Coil	Toshiba Medical Systems Corp.

The Toshiba 1.5T Extra Large Knee Coil and the predicate device have the same intended use as well as similar designs and are constructed of similar materials. Specifically, the enclosure materials used in Toshiba 1.5T Extra Large Knee Coil have been previously cleared under K072935 and K093667.

11. Non-Clinical Tests

The Toshiba 1.5T Extra Large Knee Coil was tested to and found complaint with IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, 1988 plus Amendments 1 (1991) and 2 (1995).
The coil SAR complies with the requirements of IEC 60601-2-33, Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis, 2002 plus Amendment 1 (2005).
The signal-to-noise ratio (SNR) was measured according to Toshiba Medical Systems Corporation's internal protocol.

12. Conclusion

It is the opinion of Quality Electrodynamics that the Toshiba 1.5T Extra Large Knee Coil is substantially equivalent to the above-listed legally marketed predicate devices. Use of the Quality Electrodynamics coil does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Quality Electrodynamics
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

FEB 25 2011

Re: K103185
Trade/Device Name: Toshiba 1.5T Extra Large Knee Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: January 12, 2011
Received: January 13, 2011

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K103185

Indications for Use

510(k) Number (if known): _____

Device Name:
Toshiba 1.5T Extra Large Knee Coil

Indications for Use:

For use with a Toshiba 1.5T EXCELART Vantage or 1.5T Vantage Titan magnetic resonance scanner to produce diagnostic images of the knee that can be interpreted by a trained physician.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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