K082636

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 25 2008

1. Applicant

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

2. Contact

Christie Zydyk, MBA
VP & GM, Regulatory Affairs, Quality Assurance, & Corporate Communications

3. Date prepared:

August 21, 2008

4. Tradename

TxRx 15Ch Knee Coil 1.5T
TxRx 15Ch Knee Coil 3T
TxRx CP Extremity Coil 3T

5. Common name

Coil, magnetic resonance, specialty

6. Classification

21 CFR 892.1000

7. Equivalent Device

HRK-63 Knee Array Coil and HRK-123 Knee Array Coil by MRI Devices
Leo III Tx/Rx Quadrature Knee Coil by USA Instruments

8. Device Description

The 1.5T and 3T array coils consist of a birdcage volume transmit coil and an array of 15 local receive coils. The 3T CP Knee coil consists of a birdcage coil, which is used as a volume transmit coil and also as a receive coil.

The coil elements are enclosed in a rigid plastic housing which is fire-rated and has impact and tensile strength. The split-top mechanical housing is designed to accommodate patients of various sizes. The knee coil is mounted on a rigid base which allows the coil to move freely in the left-to-right direction to accommodate imaging of both patient knees. Foam pads also aid in positioning and enhance patient comfort.

9. Intended Use

For use with a 1.5T Siemens Avanto/Espree or 3T Siemens Trio/Verio 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) #	Device	Manufacturer
K032633	HRK-63 Knee Array Coil	MRI Devices
K050299	HRK-123 Knee Array Coil	MRI Devices
K023982	Leo III Tx/Rx Quadrature Knee Coil	USA Instruments

The 1.5T and 3T Siemens knee coils and predicate devices are designed for use in conjunction with magnetic resonance scanners to produce diagnostic images of the knee that can be interpreted by a trained physician. The 1.5T and 3T Siemens knee coils and the predicate devices have similar designs and are constructed of similar materials. The main differences are the number of channels in the array coils.

11. Conclusion

It is the opinion of Quality Electrodynamics that the 1.5T and 3T Siemens knee coils are substantially equivalent to the above-listed legally marketed predicate devices. Use of the Quality Electrodynamics coils does not result in any new potential hazards

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2008

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

Re: K082636
Trade/Device Name: TxRx 15Ch Knee Coil 1.5T, TxRx 15Ch Knee Coil 3T, and TxRx CP Extremity Coil 3T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: September 9, 2008
Received: September 10, 2008

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 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082636

Device Name:

TxRx 15Ch Knee Coil 1.5T
TxRx 15Ch Knee Coil 3T
TxRx CP Extremity Coil 3T

Indications for Use:

For use with a 1.5T Siemens Avanto/Espree or 3T Siemens Trio/Verio magnetic resonance scanner to produce diagnostic images of the knee that can be interpreted by a trained physician.

Prescription Use X
(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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082636