DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 29, 2016

Quality Electrodynamics, LLC
% Ms. Kathleen Aras
Director, Regulatory and Quality Affairs
6655 Beta Drive, Suite 100
MAYFIELD VILLAGE OH 44143

Re: K163066
Trade/Device Name: TxRx Knee 15 Flare MR Coil 3.0T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: October 31, 2016
Received: November 2, 2016

Dear Ms. Aras:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163066

Device Name
TxRx Knee 15 Flare MR Coil 3.0T

Indications for Use *(Describe)*
The TxRx Knee 15 Flare MR Coil 3.0T is intended for use with Siemens 3.0T MR systems to produce diagnostic images of the knee that can be interpreted by a trained physician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. Applicant

Quality Electrodynamics, LLC. (QED)
6655 Beta Drive, Suite 100
Mayfield Village, OH 44143

2. Contact

Kathleen Aras
Director, Regulatory and Quality Affairs
(440) 484-2964
kathleen.aras@qualedyn.com

3. Date Prepared

31 October 2016

4. Tradenames

TxRx Knee 15 Flare MR Coil 3.0T

5. Common name

Coil, magnetic resonance, specialty

6. Model Numbers

QED Model Number: Q7000168

7. Classification

Magnetic resonance diagnostic device (21 CFR 892.1000, Product Code MOS, Class II)

8. Unmodified Device

3.0T TxRx 15Ch Knee Coil, Quality Electrodynamics, LLC., K082636

9. Device Description

The TxRx Knee 15 Flare MR Coil 3.0T is a transmit/receive, 15-channel phased array coil designed for magnetic resonance imaging (MRI) using the Siemens 3.0T MR systems. The TxRx Knee 15 Flare MR Coil 3.0T is intended to be used for imaging the knee.

The TxRx Knee 15 Flare MR Coil 3.0T is a reusable, non-invasive device with limited exposure with regard to duration of contact with the body. All coil elements are enclosed in a rigid plastic housing which is fire-rated, has impact and tensile strength, and has been tested for biocompatibility.

10. Indications for Use

The TxRx Knee 15 Flare MR Coil 3.0T is intended for use with Siemens 3.0T MR systems to produce diagnostic images of the knee that can be interpreted by a trained physician.

The Indications for Use statement for the modified TxRx Knee 15 Flare MR Coil 3.0T is not identical to the unmodified device (3.0T TxRx 15Ch Knee Coil); however, the differences do not alter the intended diagnostic use of the device nor do they affect the safety and effectiveness of the device relative to the unmodified device. Both Indications for Use statements for the modified TxRx Knee 15 Flare MR Coil 3.0T and unmodified 3.0T TxRx 15Ch Knee Coil indicate that the device is intended to be used in conjunction with a 3.0T MR system to produce images of the knee and that the images can be interpreted by a trained physician.

11. Summary of Technological Characteristics Compared to the Unmodified Device

At a high level, the modified device and unmodified device are based on the following same technological elements:

- Transmit/receive phased array RF coils
- Active PIN diode switching blocking circuitry. Passive blocking circuitry.
- Split-top mechanical design with an inner cross section shaped to fit the knee and leg
- Polycarbonate housing material

The following technological differences exist between the modified device and unmodified device:

- Changes to ergonomics of patient-user interface such as modified system cable connector and the use of one system cable (modified device) in comparison to two system cables (unmodified device)
- Changes to dimensional specifications of the mechanical design of the enclosure

12. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

All surface materials on the TxRx Knee 15 Flare MR Coil 3.0T that are intended to come into direct or indirect contact with patient biological tissues, cells or body fluids have a history of safe use in previously-cleared devices.

Electrical Safety and Electromagnetic Compatibility

The TxRx Knee 15 Flare MR Coil 3.0T was tested to and found to be compliant with AAMI/ANSI ES60601-1 and IEC 60601-2-33.

Surface heating was tested in accordance with AAMI/ANSI ES60601-1. The measured temperature of the surface of the coil never exceeded the maximum limit of 41^{o}C.

SAR measurement testing was performed per NEMA MS-8 to provide data supporting that the partial body limits for SAR are controlled within the limits described in IEC 60601-2-33. The testing showed that the system controls the SAR limits for the TxRx Knee 15 Flare MR Coil 3.0T such that they remain below the IEC 60601-2-33 partial body limits.

Performance Testing - Bench

The SNR and uniformity of the TxRx Knee 15 Flare MR Coil 3.0T was analyzed per IEC 62464 and was found to conform to predetermined acceptance criteria.

Performance Testing – Clinical

In accordance with the *FDA Guidance for Industry: Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices*, clinical images from volunteer scanning of the knee were obtained from the TxRx Knee 15 Flare MR Coil 3.0T. These images were used to demonstrate that the TxRx Knee 15 Flare MR Coil 3.0T produces diagnostic quality images of the intended anatomy.

13. Conclusion

The electrical safety and electromagnetic compatibility and biocompatibility data support the safety of the TxRx Knee 15 Flare MR

Coil 3.0T and the bench testing per the IEC standards and diagnostic quality sample clinical images demonstrates the performance and effectiveness of the device under the specified use conditions. This testing demonstrates that the TxRx Knee 15 Flare MR Coil 3.0T performs as well as or better than the unmodified device.