DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 6, 2017

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

Re: K162946
Trade/Device Name: 8ch Knee-Foot SPEEDER
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: October 19, 2016
Received: October 21, 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,

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)*
K162946

Device Name
8ch Knee-Foot SPEEDER

Indications for Use *(Describe)*
The 8ch Knee-Foot SPEEDER Coil is intended for use with Toshiba 1.5T MR systems to produce diagnostic images of the knee, wrist, hand, foot and ankle 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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

19 October 2016

4. Tradenames

8ch Knee-Foot SPEEDER

5. Common name

coil, magnetic resonance, specialty

6. Model Numbers

QED Model Number: Q7000172

Toshiba Model Number: MJAJ-257A

This device is manufactured and sold by QED to Toshiba. Toshiba sells the device to end users under their own model number.

7. Classification

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

8. Predicate Device

8ch Knee SPEEDER, Quality Electrodynamics, K152695

9. Device Description

The 8ch Knee-Foot SPEEDER coil is a receive-only, 8-channel phased array coil designed for magnetic resonance imaging (MRI) using the

Toshiba 1.5T MR systems. The 8ch Knee-Foot SPEEDER coil is intended to be used for imaging the knee, wrist, hand, foot and ankle.

The 8ch Knee-Foot SPEEDER coil 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 flame and impact resistant, and has been tested for biocompatibility.

The 8ch Knee-Foot SPEEDER coil also includes the comfort pads listed in Table 10-1, which are provided with the coil shipment.

Table 10-1: 8ch Knee-Foot SPEEDER Coil Comfort Pads

QED Part Number	Description	Qty
3003890	Anterior Knee Pad (1/4" Thick Pad)	1
3003864	Posterior Knee Support Pad (Bottom Thermoformed Pad)	1
3003866	Free Leg Pad (Non-Imaged Knee Pad)	1
3003865	Inferior Leg Pad (Foot/Ankle Pad)	1
3004802	Ankle / Heel support pad for foot imaging	1
3004823	Wedge pad for foot imaging	1

10. Indications for Use

The 8ch Knee-Foot SPEEDER Coil is intended for use with Toshiba 1.5T MR systems to produce diagnostic images of the knee, wrist, hand, foot and ankle that can be interpreted by a trained physician.

The Indications for Use statement for the 8ch Knee-Foot SPEEDER coil is not identical to that of the predicate device; 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 predicate. The proposed 8ch Knee-Foot SPEEDER coil is a modification to the predicate 8ch Knee SPEEDER coil that expands the intended use from knee, wrist, hand and forefoot to knee, wrist, hand, foot and ankle; thereby encompassing the whole foot and ankle. This is accomplished by adding a second anterior piece used for foot and ankle imaging. The posterior and knee anterior piece remain identical to the predicate 8ch Knee SPEEDER coil cleared under K152695.

11. Summary of Technological Characteristics Compared to the Predicate Device

At a high level, the subject and predicate devices are based on the following same technological elements:

- Intended to provide images of the knee, wrist and hand regions
- 8-channel, receive-only, phased array RF coils
- Split-top mechanical design
- Housing materials are flame, impact resistant and biocompatible
- Knee, wrist, and hand imaging accomplished through 8ch Knee SPEEDER configuration
- Compatible with Toshiba 1.5T MR systems

The following technological differences exist between the subject and predicate device:

- Intended to provide images of the foot and ankle regions (subject) versus forefoot region (predicate) in addition to knee, wrist and hand
- Two anterior pieces with split-top mechanical design shaped to fit the knee and foot (subject) versus single split-top mechanical design shaped to fit the knee (predicate)

12. Performance Data

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

Biocompatibility Testing

All surface materials on the 8ch Knee-Foot SPEEDER coil 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 electrical safety and electromagnetic compatibility of the 8ch Knee-Foot SPEEDER coil was verified in accordance 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.

Performance Testing - Bench

The SNR and uniformity of the 8ch Knee-Foot SPEEDER was analyzed per NEMA MS 6 and NEMA MS 9 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, wrist, hand, foot and ankle were obtained from the 8ch Knee-Foot SPEEDER. These images were used to demonstrate that the 8ch Knee-Foot SPEEDER produces diagnostic quality images of the intended anatomies.

13. Conclusion

The electrical safety and electromagnetic compatibility and biocompatibility data support the safety of the 8ch Knee-Foot SPEEDER and the bench testing per the NEMA standards demonstrates the performance and effectiveness of the device under the specified use conditions. This testing demonstrates that the 8ch Knee-Foot SPEEDER performs as well as or better than the predicate device.