Quality Electrodynamics, LLC
Eric Yeh
Senior Regulatory Affairs Specialist
6655 Beta Drive Suite 100
Mayfield Village, Ohio 44143

July 10, 2018

Re: K181697
Trade/Device Name: 16ch Foot/ Ankle SPEEDER
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: June 26, 2018
Received: June 27, 2018

Dear Eric Yeh:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Patrick Hintz -S

Digitally signed by Patrick Hintz -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Patrick Hintz -S, 0.9.2342.19200300.100.1.1=1001038110
Date: 2018.07.11 09:07:09 -04'00'

for

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k181697

Device Name
16ch Foot/Ankle SPEEDER

Indications for Use *(Describe)*
The 16ch Foot/Ankle SPEEDER coil is intended for use with Canon 3.0T MR systems to produce diagnostic images of the 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Applicant

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

2. Contact

Eric Yeh
Senior Regulatory Affairs Specialist
(440) 484-2940
eric.yeh@qualedyn.com

3. Date Prepared

26 June 2018

4. Tradenames

16ch Foot/Ankle SPEEDER

5. Common name

Coil, magnetic resonance, specialty

6. Model Numbers

QED Model Number: Q7000073

Canon Model Number: MJAJ-262A

This device is manufactured and sold by QED to Canon. Canon 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 Devices

Shoulder SPEEDER, Quality Electrodynamics, K102489

9. Device Description

The 16ch Foot/Ankle SPEEDER is a receive-only, 16-channel phased array coil designed for magnetic resonance imaging (MRI) using Canon 3.0T MR systems. The 16ch Foot/Ankle SPEEDER is intended to be used for foot and ankle imaging.

The 16ch Foot/Ankle SPEEDER is a reusable, non-invasive device with limited exposure with regard to duration of contact with the body. All coil elements are enclosed in either a rigid plastic housing which is fire-rated, has impact and tensile strength, and has been tested for biocompatibility, or fire-rated flexible flaps that do not come into direct contact but can be easily adjusted to accommodate patients.

10. Indications for Use

The 16ch Foot/Ankle SPEEDER is intended for use with Canon 3.0T MR systems to produce diagnostic images of the foot and ankle that can be interpreted by a trained physician.

The Indications for Use statement for the 16ch Foot/Ankle SPEEDER 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. Both Indications for Use statements for the 16ch Foot/Ankle SPEEDER and predicate Shoulder SPEEDER indicate that the device is intended to be used in conjunction with a 3.0T MR scanner to produce images of intended anatomies that can be interpreted by a trained physician. The indications for use statements differ only in that the proposed 16ch Foot/Ankle SPEEDER is intended to provide images of foot and ankle anatomies (subject) versus shoulder (predicate) and channel count of 16 (subject) versus 6 (predicate).

11. Summary of Technological Characteristics Compared to the Predicate Device

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

- Field strength of MR system (3T)
- Receive-only, phased array RF coil
- Rigid enclosure contoured to fit anatomy with flexible flaps adjusted to accommodate patients

- Housing materials are flame, impact resistant and biocompatible

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

- Intended to provide images of anatomies (foot and ankle (proposed) versus shoulder (predicate))
- Channel Count (16 (proposed) versus 6 (predicate))

12. Performance Data

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

Biocompatibility Testing

All surface materials on the 16ch Foot/Ankle SPEEDER 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 16ch Foot/Ankle SPEEDER 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 16ch Foot/Ankle 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 foot and ankle were obtained from the 16ch Foot/Ankle SPEEDER. These images were used to demonstrate that the 16ch Foot/Ankle SPEEDER produces diagnostic quality images of the intended anatomy.

13. Conclusion

The electrical safety and electromagnetic compatibility and biocompatibility data support the safety of the 16ch Foot/Ankle SPEEDER and the bench testing per the NEMA 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 16ch Foot/Ankle SPEEDER performs as well as or better than the predicate device.