



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

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

December 16, 2016

Re: K162623

Trade/Device Name: 16ch T/R Hand Wrist Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: September 19, 2016
Received: September 20, 2016

Dear Ms. Aras:

This letter corrects our substantially equivalent letter of December 9, 2016.

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent watermark of the FDA logo.

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

Indications for Use

510(k) Number (if known)

K162623

Device Name

16ch T/R Hand Wrist Coil

Indications for Use (Describe)

The 16ch T/R Hand Wrist Coil is intended for use with GE 3.0T MR systems to produce diagnostic images of the hand and wrist 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“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

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

3. Date Prepared

19 September 2016

4. Tradenames

16ch T/R Hand Wrist Coil

5. Common name

Coil, magnetic resonance, specialty

6. Model Numbers

QED Model Number: Q7000152

GE Model Number: 5561531-2

This device is manufactured and sold by QED to GE. GE 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

1.5T 16-Channel Hand-Wrist Coil, Invivo Corporation, K103149 (Primary Predicate)

18Ch T/R Knee Coil, Quality Electrodynamics, LLC., K150331 (Secondary Predicate)

9. Device Description

The 16ch T/R Hand Wrist Coil is a transmit/receive, 16-channel phased array coil designed for magnetic resonance imaging (MRI) using the GE 3.0T MR systems. The 16ch T/R Hand Wrist Coil is intended to be used for imaging the hand and wrist.

The 16ch T/R Hand Wrist 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 fire-rated, has impact and tensile strength, and has been tested for biocompatibility.

10. Indications for Use

The 16ch T/R Hand Wrist Coil is intended for use with GE 3.0T MR systems to produce diagnostic images of the hand and wrist that can be interpreted by a trained physician.

The Indications for Use statement for the 16ch T/R Hand Wrist coil is not identical to that of the predicate devices; 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 predicates. Both Indications for Use statements for the 16ch T/R Hand Wrist coil and primary predicate 1.5T 16-Channel Hand-Wrist Coil indicate that the device is intended to be used in conjunction with a MR scanner to produce images of the hand and wrist that can be interpreted by a trained physician. The indications for use statements differ only in that the proposed 16ch T/R Hand Wrist coil is intended to be used with 3.0T MR systems rather than 1.5T MR systems.

The secondary predicate 18ch T/R Knee Coil utilizes the same transmit-receive technology, utilizes same materials, and is similarly compatible with 3.0T MR systems as the proposed 16ch T/R Hand Wrist coil.

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 hand and wrist (primary predicate)
- 16 channels (primary predicate)
- Transmit/receive, phased array RF coils (secondary predicate)

- Hinged “clamshell” mechanical design (primary predicate)
- Housing materials are flame, impact resistant and biocompatible (secondary predicate)
- Compatible with GE 3.0T MR systems (secondary 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 T/R Hand Wrist 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 16ch T/R Hand Wrist coil 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°C.

A finite-difference time-domain electromagnetic simulation was performed to provide data supporting that the partial body limits for SAR are controlled within the limits described in IEC 60601-2-33. The simulation showed that the local SAR limits for the 16ch T/R Hand Wrist coil are below the IEC 60601-2-33 partial body limits.

Performance Testing - Bench

The SNR and uniformity of the 16ch T/R Hand Wrist coil was analyzed per NEMA MS 1 and NEMA MS 3 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 hand and wrist were obtained from the 16ch T/R Hand Wrist coil. These images were used to demonstrate that the 16ch T/R Hand Wrist coil 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 T/R Hand Wrist coil 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 T/R Hand Wrist coil performs as well as or better than the predicate devices.