DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 22, 2014

QUALITY ELECTRODYNAMICS, LLC.
KATHLEEN ARAS
DIRECTOR, REGULATORY AND QUALITY AFFAIRS
700 BETA DRIVE, SUITE 100
MAYFIELD VILLAGE OH 44143

Re: K142002
Trade/Device Name: Breast SPEEDER CX and Grid Holder CX Kit
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 21, 2014
Received: July 23, 2014

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

Janine M. Morris
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)*

Device Name
Breast SPEEDER CX

Indications for Use *(Describe)*
The Breast SPEEDER CX is intended for use with Toshiba 1.5T MRI systems to produce diagnostic images of the breast anatomy 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
PRAStaff@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."

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)*

Device Name
Grid Holder CX

Indications for Use *(Describe)*
The Grid Holder CX kit is intended for use with the Breast SPEEDER CX to permit access to the breast anatomy for biopsy and lesion localization procedures.

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.

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510(k) Summary

1. Applicant

Quality Electrodynamics, LLC. (QED)
700 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

21 July 2014

4. Tradenames

Breast SPEEDER CX

Grid Holder CX Kit

5. Common name

Coil, magnetic resonance, specialty

6. Classification

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

7. Predicate Device

Vanguard Breast MRI Auxiliary Table with 8 Channel Coil Array, Sentinelle Medical, Inc., K060873

No reference devices were used in this submission.

8. Device Description

The Breast SPEEDER CX is a receive-only, eight-channel phased array coil designed for magnetic resonance imaging (MRI) using the Toshiba 1.5T MR systems. The Breast SPEEDER CX is intended to be used for imaging the breast anatomy.

Similar to other breast coils, the Breast SPEEDER CX includes apertures through which the breasts are admitted. The Breast SPEEDER CX includes compression plates which allow compression and immobilization of the breast. Breasts may be imaged individually or simultaneously.

The Breast SPEEDER CX also includes the accessories listed in Table 0-1. The accessories consist of pads and a head rest intended to increase patient comfort during scanning.

Table 0-1: Breast SPEEDER CX Accessories

QED Part Number	Description	Qty
3003080	Comfort pad	1
3003081	Sternum pad	1
3003084	Medial pad	2
3003082	Transition pad	1
3003079	Head rest pad	1
2000588	Head rest	1
3003225	Compression Plate	2
3003085	Breast Riser CX (optional)	1

The Grid Holder CX Kit is an optional kit offered separately and is intended to be used to allow access to the breast for interventional procedures, such as biopsy and lesion localization. When the Grid Holder CX is used with the Breast SPEEDER CX, the lateral coils are replaced with the biopsy adaptor, which is fitted with either a grid or a post and pillar device, both commercially available. Compatible biopsy grids and post and pillar biopsy devices are available from NORAS MRI Products GmbH and include the items listed in Table 0-2. The breast can be accessed and interventional procedures performed from either the lateral or medial directions.

Table 0-2: Devices Compatible with the Grid Holder CX

Part Number	Description
117143	NORAS Height Adjustable Grid, Lateral, Re-usable
112235	NORAS Grid Lateral, Disposable
112238	NORAS Grid Medial, Disposable
117884	NORAS Pillar and Post Adapter, Re-usable
117139	NORAS Vertically Curved Slat Plate, Re-usable
111301	NORAS Horizontally Curved Slat Plate, Re-usable

The Breast SPEEDER CX and Grid Holder CX Kit are reusable, non-invasive devices 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.

9. Indications for Use

The Breast SPEEDER CX is intended for use with Toshiba 1.5T MR systems to produce diagnostic images of the breast anatomy that can be interpreted by a trained physician.

The Grid Holder CX kit is intended for use with the Breast SPEEDER CX to permit access to the breast anatomy for biopsy and lesion localization procedures.

The Indications for Use statements for the Breast SPEEDER CX and Grid Holder CX are not identical to 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 indicate that the device is intended to be used in conjuction with an MR system to produce images of the breast, that the images can be interpreted by a trained physician, and that when used with additional equipment, the device permits access to the breast anatomy for biopsy and localization procedures. The Indications for Use statements differ in that the Indications for Use statement for the predicate device encompasses both the imaging and breast access aspects of the device whereas, since the Breast SPEEDER CX and Grid Holder CX are sold separately, the subject's Indication for Use statement has been separated into two parts that address the

imaging and breast access aspects specific to the two products separately.

10. Summary of Technological Characteristics Compared to the Predicate Device

The Breast SPEEDER CX and the Vanguard Breast MRI Auxiliary Table with 8 Channel Coil Array are both 8-channel, receive-only, phased array RF coils intended to be used with a 1.5T MR system to provide images of the breast. When the Grid Holder CX is used with the Breast SPEEDER CX, both devices allow access to the breast for biopsy and localization procedures.

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

- RF coils intended to provide images of the breast anatomy
- Compatible with 1.5T MR systems
- 8-channel, receive-only, phased array coil design
- Active PIN diode switching blocking circuitry. Passive blocking circuitry.
- Supports a patient in a prone position, with apertures through which the breasts are admitted
- Includes compression plates which allow compression and immobilization of the breast.
- Allows access to the breast for biopsy and localization procedures

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

- MR system compatibility (Toshiba (subject) versus GE (predicate))

11. Performance Data

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

Biocompatibility Testing

The only patient contact material on the Breast SPEEDER CX and Grid Holder CX is Lexan 940A polycarbonate painted with Polane S

polyurethane enamel. Both the polycarbonate and the polyurethane enamel have a history of use in MR applications and other medical devices. For example, these materials were patient contact materials in the devices cleared through 510(k) numbers K122638 and K140998.

Electrical Safety and Electromagnetic Compatibility

The Breast SPEEDER CX was tested to and found to be compliant with AAMI/ANSI ES60601-1 and IEC 60601-2-33.

Surface heating was tested in both plugged in and unplugged configurations according to AAMI/ANSI ES60601-1. The measured temperature of the surface of the coil never exceeded the maximum limit of 41^{o}C in either configuration.

Bench Testing

The SNR and uniformity of the Breast SPEEDER CX was analyzed per and found to conform to NEMA MS 9-2008.

12. Conclusion

The electrical safety and electromagnetic compatibility and biocompatibility data support the safety of the Breast SPEEDER CX 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 Breast SPEEDER CX performs comparably to the predicate device.