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

November 17, 2017

Re: K173446
Trade/Device Name: Contour 24
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: November 6, 2017
Received: November 6, 2017

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Robert Ochs

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173446

Device Name
Contour 24

Indications for Use *(Describe)*
The Contour 24 is intended for use with Siemens 3.0T MR systems to produce diagnostic images of general human 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)

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

3. Date Prepared

9 November 2017

4. Tradenames

Contour 24

5. Common name

Coil, magnetic resonance, specialty

6. Model Numbers

QED Model Number: Q7000184

7. Classification

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

8. Predicate Device

Siemens 3.0T Blanket Array Coil manufactured by Resonance Innovations LLC., K142755

9. Device Description

The Contour 24 is a receive-only, 24-channel phased array coil designed for magnetic resonance imaging (MRI) using the Siemens 3.0T MR systems. The Contour 24 is intended to be used for imaging general human anatomy, such as the abdomen and pelvis.

The Contour 24 is a reusable, non-invasive device with limited exposure with regard to duration of contact with the body. The coil elements are encapsulated in polycarbonate and aramid felt which are fire-rated and provide impact and tensile strength, then covered with a polyurethane coated nylon fabric which has been evaluated for biocompatibility.

10. Indications for Use

The Contour 24 is intended for use with Siemens 3.0T MR systems to produce diagnostic images of general human anatomy that can be interpreted by a trained physician.

The Indications for Use statement for the Contour 24 is identical to the predicate device (Siemens 3.0T Blanket Array Coil); neither the intended diagnostic use nor safety or effectiveness of the device relative to the predicate device has been altered. Both Indications for Use statements for the proposed Contour 24 and predicate Siemens 3.0T Blanket Array Coil indicate that the device is intended to be used in conjunction with a 3.0T MR system to produce images of general human anatomy and that the images can be interpreted by a trained physician.

11. Predicate Device and Technological Characteristics

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

- Receive-only phased array RF coil
- Active PIN diode switching blocking circuitry. Passive blocking circuitry.
- Flexible blanket-like enclosure
- Compatible with Siemens 3.0T MR systems

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

- Materials used for flame retardancy and biocompatibility:
  Polycarbonate and aramid felt with a polyurethane coated nylon fabric (proposed device) versus EVA foam with a nylon fabric or compressed EVA cover (predicate device)

12. Performance Data

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

Biocompatibility Testing

All surface materials on the Contour 24 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 Contour 24 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.

Performance Testing - Bench

The SNR and uniformity of the Contour 24 was analyzed per 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 general human anatomy were obtained from the Contour 24. These images were used to demonstrate that the Contour 24 produces diagnostic quality images of the intended anatomies.

13. Conclusion

The electrical safety and electromagnetic compatibility and biocompatibility data support the safety of the Contour 24 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 Contour 24 performs as well as or better than the predicate device.