Quality Electrodynamics, LLC
℅ Mr. Eric Yeh
Senior Regulatory Affairs Specialist
6655 Beta Drive, Suite 100
MAYFIELD VILLAGE OH 44143

January 3, 2020

Re: K193140
Trade/Device Name: Flex Body SPEEDER
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: November 11, 2019
Received: November 13, 2019

Dear Mr. 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K193140

Device Name
Flex Body SPEEDER

Indications for Use *(Describe)*
The Flex Body SPEEDER is intended for use with Canon 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.

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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

11 November 2019

4. Tradenames

Flex Body SPEEDER

5. Common name

Coil, magnetic resonance, specialty

6. Model Numbers

QED Model Number: Q7000199

7. Classification

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

8. Predicate Device

Contour 24 manufactured by Quality Electrodynamics, LLC., K173446

9. Device Description

The Flex Body SPEEDER is a receive-only, phased array coil designed for magnetic resonance imaging (MRI) using the Canon 3T MR systems. The Flex Body SPEEDER is intended to be used for imaging general human anatomy, such as the torso, pelvis, joints, bones and extremities.

The Flex Body SPEEDER 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 Flex Body SPEEDER is intended for use with Canon 3T 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 Flex Body SPEEDER is not identical to that of the predicate device (Contour 24); however, the differences do not alter the intended diagnostic use of the device nor do they affect the safety or effectiveness of the device relative to the predicate device. Both Indications for Use statements for the proposed Flex Body SPEEDER and predicate Contour 24 indicate that the device is intended to be used in conjunction with a 3T MR system to produce images of general human anatomy and that the images can be interpreted by a trained physician. The indications for use statements differ only in that the proposed Flex Body SPEEDER is intended to be used with 3T Canon MR systems instead of 3T Siemens MR systems.

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
- Materials used for flame retardancy and biocompatibility:
  Polycarbonate and aramid felt with a polyurethane coated nylon fabric

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

- Compatible with Canon 3T MR systems (proposed device) versus compatible with Siemens 3T MR systems (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 Flex Body 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. The material and processing methods used in the proposed device are identical to those used in previously-cleared devices. The medical device in its final finished form is identical to previously-cleared devices in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Electrical Safety and Electromagnetic Compatibility

The Flex Body SPEEDER 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.

Electrostatic Discharge Immunity was tested in accordance with IEC 60601-1-2 Ed 4.0 (2014) utilizing IEC 61000-4-2:2008, Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test as the methodology. The Canon 3T Flex Body SPEEDER Coil was found to be in compliance with IEC 60601-1-2 Ed 4.0 (2014) for electrostatic discharge immunity.

Performance Testing - Bench

The SNR and uniformity of the Flex Body 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 general human anatomy were obtained from the Flex Body SPEEDER. These images were

used to demonstrate that the Flex Body 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 Flex Body SPEEDER 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 Flex Body SPEEDER performs as well as or better than the predicate device.