February 28, 2025

Quality Electrodynamics
Jovanna Boudreaux
Senior Quality/ Regulatory Engineer
6655 Beta Drive
Ste 100
Mayfield Village, Ohio 44122

Re: K244054
Trade/Device Name: 16ch Flex SPEEDER Medium 1.5T (Q7000246);
16ch Flex SPEEDER Large 1.5T (Q7000247)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: December 30, 2024
Received: December 31, 2024

Dear Jovanna Boudreaux:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K244054

Device Name

16ch Flex SPEEDER Medium 1.5T (Q7000246);
16ch Flex SPEEDER Large 1.5T (Q7000247)

Indications for Use *(Describe)*

The 16CH Flex SPEEDER Medium is intended for use with Canon 1.5T MR systems to produce diagnostic images of general human anatomy that can be interpreted by a trained physician.

The 16ch Flex SPEEDER Large coil is intended for use with Canon 1.5T 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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510(k) #: K244054

510(k) Summary

Prepared on: 2025-02-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Quality Electrodynamics
Applicant Address	6655 Beta Drive STE 100 Mayfield Village OH 44122 United States
Applicant Contact Telephone	4404842340
Applicant Contact	Mrs. JoVanna Boudreaux
Applicant Contact Email	jovanna.boudreaux@qualedyn.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	16ch Flex SPEEDER Medium 1.5T (Q7000246); 16ch Flex SPEEDER Large 1.5T (Q7000247)
Common Name	Magnetic resonance diagnostic device
Classification Name	Coil, Magnetic Resonance, Specialty
Regulation Number	892.1000
Product Code(s)	MOS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K121362	1.5T 16ch Flex SPEEDER Coil Medium/Large	MOS

Device Description Summary

21 CFR 807.92(a)(4)

The 16ch Flex Speeder Medium and 16ch Flex Speeder Large coils are a receive-only, 16-channel phased array coil designed for magnetic resonance imaging (MRI) using the Canon 1.5T MR systems. The 16ch Flex Speeder Medium and 16ch Flex Speeder Large coils are intended to be used for general anatomies.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The 16CH Flex SPEEDER Medium is intended for use with Canon 1.5T MR systems to produce diagnostic images of general human anatomy that can be interpreted by a trained physician.

The 16ch Flex SPEEDER Large coil is intended for use with Canon 1.5T MR systems to produce diagnostic images of general human anatomy that can be interpreted by a trained physician.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use Statements for the 16ch Flex SPEEDER Medium and Large 1.5T are not identical to that of the predicate devices (1.5T 16ch Flex SPEEDER Medium and Large); however, the differences do not affect the safety or effectiveness of the device relative to the predicate device. Both Indications for Use statements for the proposed 16ch Flex SPEEDER Medium and Large 1.5Tand predicate 1.5T 16ch Flex SPEEDER Medium and Large indicate that the device is intended to be used in conjunction with a MR system to produce images of human anatomy and that the images can be interpreted by a trained physician. The indications for use statements for the proposed 16ch Flex SPEEDER Medium and Large 1.5T and predicate devices differ only in that the proposed devices are indicated for use

in general human anatomy whereas the predicate devices are indicated for use in various specific anatomies that comprise general human anatomy.

Technological Comparison

21 CFR 807.92(a)(6)

At a high level, the proposed 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.
• Materials used for impact protection and biocompatibility: Polycarbonate with a polyurethane coated nylon fabric cover

No technological differences exist between the proposed and predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The signal-to-noise ratio (SNR) and image uniformity of the 16ch Flex Speeder Coils were measured on a 1.5T Canon MR System, manufactured by Canon Medical System. The SNR and uniformity of the 16ch Flex Speeder Coils were analyzed per NEMA MS-9 (using alternate method 2.5 from MS-6) and uniformity was analyzed using NEMA MS-9 (primary method from MS-6) using pre-determined acceptance criteria.

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 a Canon 1.5T MR system. Clinical images were obtained for the 16CH Flex SPEEDER Medium and Large 1.5T from upper and lower extremities, chest, abdomen, pelvis, head, neck and spine. These images were used to demonstrate that the 16ch Flex Speeder Coils produce diagnostic quality images of the intended anatomy. No adverse events were reported or recorded.

The electrical safety and electromagnetic compatibility and biocompatibility data support the safety of the 16ch Flex Speeder Coils 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 16ch Flex Speeder Coils performs as well as or better than the predicate device.

Surface heating was tested in accordance with AAMI/ANSI EN60601-1. The device was tested plugged and unplugged. The measured temperature of the surface of the coil never exceeded the maximum limit of 41C.