



Food and Drug Administration  
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June 2, 2016

Quality Electrodynamics, LLC  
Kathleen Aras  
Director, Regulatory and Quality Affairs  
700 Beta Drive Suite 100  
Mayfield Village, Ohio 44143

Re: K161193

Trade/Device Name: 16ch Tx/Rx Knee SPEEDER  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic Resonance Diagnostic Device  
Regulatory Class: Class II  
Product Code: MOS  
Dated: April 22, 2016  
Received: April 27, 2016

Dear Kathleen 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a grey rectangular highlight behind the name.

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)

K161193

Device Name

16ch Tx/Rx Knee SPEEDER

Indications for Use (Describe)

The 16ch Tx/Rx Knee SPEEDER is intended for use with Toshiba 1.5T MR systems to produce diagnostic images of the knee, wrist, hand, and forefoot 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.\***

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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

22 April 2016

### 4. Tradenames

16ch Tx/Rx Knee SPEEDER

### 5. Common name

Coil, magnetic resonance, specialty

### 6. Model Numbers

QED Model Number: Q7000160

Toshiba Model Number: MJAJ-237A

This device is manufactured and sold by QED to Toshiba. Toshiba 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 Device

16ch Tx/Rx Knee SPEEDER, Quality Electrodynamics, LLC. K151753

## 9. Device Description

The 16ch Tx/Rx Knee SPEEDER is a transmit/receive, 16-channel receive coil, switchable between 15-channel receive array and 1-channel birdcage receive, and designed for magnetic resonance imaging (MRI) using Toshiba 1.5T MRI systems. The 16ch Tx/Rx Knee SPEEDER is intended to be used for imaging the knee, wrist, hand and forefoot.

The 16ch Tx/Rx Knee SPEEDER 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.

The 16ch Tx/Rx Knee SPEEDER also includes the comfort pads listed in Table 1. The coil is provided with comfort pads.

**Table 1: 16ch Tx/Rx Knee SPEEDER Comfort Pads**

| <b>QED Part Number</b> | <b>Description</b>                      | <b>Qty</b> |
|------------------------|---|------------|
| 3003890                | Anterior Knee Pad (1/4" Thick Pad)      | 1          |
| 3004435                | Posterior Knee Support Pad (Bottom Pad) | 1          |
| 3003866                | Free Leg Pad (Non-Imaged Knee Pad)      | 1          |
| 3003865                | Inferior Leg Pad (Foot/Ankle Pad)       | 1          |

## 10. Indications for Use

The 16ch Tx/Rx Knee SPEEDER is intended for use with Toshiba 1.5T MR systems to produce diagnostic images of the knee, wrist, hand, and forefoot that can be interpreted by a trained physician.

The Indications for Use statement for the 16ch Tx/Rx Knee SPEEDER is 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 for the 16ch Tx/Rx Knee SPEEDER coil and predicate 16ch Tx/Rx Knee SPEEDER coil indicate that the device is intended to be used in conjunction with a MR scanner to produce images of the knee, wrist, hand and forefoot and that the images can be interpreted by a trained physician. The Indications for Use statements differ only in MR scanner field strength; the proposed 16ch Tx/Rx Knee SPEEDER coil is intended for use with a 1.5T system while the predicate is to be used with a 3.0T system.

## 11. Summary of Technological Characteristics Compared to the Predicate Device

The proposed 16ch Tx/Rx Knee SPEEDER and the predicate 16ch Tx/Rx Knee SPEEDER are both 16 channel transmit/receive phased array RF coils intended to be used with a Toshiba MR system to provide images of the knee, wrist, hand and forefoot.

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

- Intended to provide images of the knee, wrist, hand and forefoot
- 16 channel, transmit/receive phased array RF coils
- Active PIN diode switching blocking circuitry. Passive blocking circuitry.
- Split-top mechanical design with an inner cross section shaped to fit the knee.
- Polycarbonate housing material

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

- Field strength of MR system (1.5T (subject) versus 3.0T (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 Tx/Rx Knee SPEEDER that are intended to come into direct or indirect contact with patient biological tissues, cells or body fluids either have a history of safe use in previously-cleared devices or have been assessed for biocompatibility according to ISO 10993-1. Per ISO 10993-1, all patient-contacting materials on the 16ch Tx/Rx Knee SPEEDER are classified as surface-contacting, limited exposure (A) devices. Therefore, where testing was performed, the materials were tested for cytotoxicity per ISO 10993-5 and for irritation and sensitization per ISO 10993-10.

### ***Electrical Safety and Electromagnetic Compatibility***

The electrical safety and electromagnetic compatibility of the 16ch Tx/Rx Knee SPEEDER was verified in accordance 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.

Specific Absorption Rate (SAR) is controlled by the MR system, which estimates the total power delivered to the imaging volume with respect to whole body mass and estimated mass present in the imaging volume. The Toshiba MR system controls the maximum local SAR to within IEC60601-2-33 limits. SAR was tested per NEMA MS-8 on the 16ch Tx/Rx Knee SPEEDER in conjunction with the intended MR system; results showed that the measured SAR from the 16ch Tx/Rx Knee SPEEDER local transmitter was below the SAR displayed from the system. Thus, the Titan System SAR Management system effectively limits the local SAR when using the 16ch Tx/Rx Knee SPEEDER Coil.

### ***Performance Testing - Bench***

The SNR and uniformity of the 16ch Tx/Rx Knee SPEEDER was analyzed per NEMA MS-1, MS-6 and 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 the knee, hand, wrist, and forefoot were obtained from the 16ch Tx/Rx Knee SPEEDER. These images were used to demonstrate that the 16ch Tx/Rx Knee 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 16ch Tx/Rx Knee SPEEDER and the bench testing per the NEMA standards and diagnostic quality sample clinical images demonstrate the performance and effectiveness of the device under the specified use conditions. This testing demonstrates that the 16ch Tx/Rx Knee SPEEDER performs as well as or better than the predicate device.