K140998
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JUL 11 2014

Section 5: 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

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

16 April 2014

4. Tradenames

Pediatric 16

Pediatric 16, A 1.5T Tim Coil

Pediatric 16, A 3T Tim Coil

5. Common name

Coil, magnetic resonance, specialty

6. Classification

21 CFR 892.1000

7. Equivalent Device

Infant Array, Advanced Imaging Research, Inc., K113365

8. Device Description

This filing describes local RF coils intended to be used with the MAGNETOM Aera and Skyra MR systems.

The Pediatric 16 is a sixteen-channel receive-only array coil designed for magnetic resonance imaging (MRI) using the Siemens MAGNETOM Aera (1.5T) and Skyra (3T) MR systems. The Pediatric 16 is intended to be used for imaging of the head and neck of neonates and infants.

9. Indications for Use

The Pediatric 16 is intended for use with the Siemens 1.5T/3T MRI systems to produce diagnostic images of the head and neck of neonates and infants that can be interpreted by a trained physician.

10. Summary of Technological Characteristics Compared to the Predicate Device

Quality Electrodynamics believes that the Pediatric 16 is substantially equivalent to the Infant Array manufactured by Advanced Imaging Research and cleared through 510(k) #K113365 on March 29 2012.

The Pediatric 16 and the Infant Array are both receive-only, array RF coils intended to provide images of the head and neck in neonates and infants. Both the Pediatric 16 and the Infant Array are intended to be used with the Siemens 1.5T and 3T MR systems. The intended uses of the devices are essentially identical.

11. Summary of Non-Clinical Performance Testing as Basis for Substantial Equivalence

The Pediatric 16 was tested to and found to conform to 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°C in either configuration.

The SNR and uniformity of the Pediatric 16 was analyzed per and found to conform to NEMA MS 9-2008.

12. Conclusion

It is the opinion of Quality Electrodynamics that the Pediatric 16 is substantially equivalent to the above-listed, legally-marketed predicate device. Non-clinical performance testing verified that the use of the

Quality Electrodynamics coils does not result in any new potential hazards.

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

July 11, 2014

Quality Electrodynamics, LLC
% Ms. Kathleen Aras
Director, Regulatory and Quality Affairs
700 Beta Drive, Suite 100
MAYFIELD VILLAGE OH 44143

Re: K140998
Trade/Device Name: Pediatric 16, A 1.5T Tim Coil/Pediatric 16, A 3T Tim Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: April 16, 2014
Received: April 18, 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,

Michael D. O'Hara 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)*
K140998

Device Name
Pediatric 16

Indications for Use *(Describe)*
The Pediatric 16 is intended for use with the Siemens 1.5T/3T MRI systems to produce diagnostic images of the head and neck of neonates and infants 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)*

Michael D. O'Hara

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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