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

January 13, 2017

GE Healthcare Coils (USA Instruments, Inc.)
% Mary A. Mayka, Ph.D.
Regulatory Affairs Manager
1515 Danner Drive
AURORA OH 44202

Re: K163205
Trade/Device Name: 48CH Head Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 14, 2016
Received: November 15, 2016

Dear Dr. Mayka:

This letter corrects our substantially equivalent letter of January 12, 2016

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,

For

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163205

Device Name
48CH Head Coil

Indications for Use *(Describe)*

The 3.0T 48CH Head Coil is a receive-only RF coil designed for use with select 3.0T MRI systems manufactured by GE Healthcare. The coil is indicated for use for head imaging. The nucleus excited is hydrogen.

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.

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GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	January 5, 2017
Submitter:	GE Healthcare Coils (USA Instruments, Inc.) 1515 Danner Drive Aurora, OH 44202 USA
Primary Contact Person:	Mary A. Mayka, Ph.D. Regulatory Affairs Manager GE Healthcare Phone: 262-527-3148 Fax: 262-364-2785
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director GE Healthcare Phone: 262-521-6848 Fax: 262-364-2785
Device Trade Name:	48CH Head Coil
Common/Usual Name:	Coil, Magnetic Resonance, Specialty
Classification Names:	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000
Product Code:	MOS
Predicate Device(s):	TDI Head Neck Unit (K143345)
Device Description:	The 48CH Head Coil is a phased-array receive-only coil designed to provide optimum signal-to noise, uniform coverage and high acceleration including multiband imaging of the head and brain. It is a 48-element coil tuned to image proton nuclei and designed for use with GE 3.0T MRI Systems. Each coil element has an integrated preamplifier to improve image quality and a custom MEMS (Micro Electro Mechanical System) switch to decouple the receive coil from the MR System body coil. The 48CH Head Coil has an anterior coil and a posterior coil with P-connectors. The coil has optimized pads to maximize patient comfort and image uniformity.

Intended Use:	The 3.0T 48CH Head Coil is a receive-only RF coil designed for use with select 3.0T MRI systems manufactured by GE Healthcare. The coil is indicated for use for head imaging. The nucleus excited is hydrogen.
Comparison of Intended Use:	Both the 48CH Head Coil and the predicate device are classified as coils for magnetic resonance imaging devices and are intended for diagnostic use. Both indications for use statements are functional in nature, and do not list specific diseases or conditions. The 48CH Head Coil and the predicate device are indicated for the same patient population, and for the same clinical setting. The predicate device, the TDI Head Neck Unit is one coil as part of the TDI Coil Suite, and covers head, neck, brachial-plexus and vessel anatomies. The 48CH Head Coil also references head anatomy. Therefore, GE Healthcare believes that the 48CH Head Coil has the same intended use as the predicate device in accordance with the FDA's guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", dated 28 July 2014.
Comparison of Technological Characteristics:	Overall, the 48CH Head Coil employs the same fundamental scientific technology as its predicate device. Coil Design: The most notable technological difference between the 48CH Head Coil and the predicate device is that the 48CH Head Coil contains 48 elements and utilizes MEMS technology for decoupling as compared to the predicate's 21 elements and hybrid decoupling. Operating Principles: The 48CH Head Coil operates on the same principles as the predicate device. Materials: The 48CH Head Coil and the predicate device both use flame retardant materials. Safety and Performance Testing: Both the 48CH Head Coil and the predicate device complies with the same safety and performance testing (see Determination of Substantial Equivalence, below). These technological differences do not raise any different questions of safety and effectiveness.

Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The predicate and modified devices have been subject to similar risk management testing to demonstrate substantial equivalence of safety and performance. Testing included: • AAMI/ANSI ES60601-1 • IEC 60601-1-2 • IEC 60601-2-33 • MS 6-2008 • Maximum B1 peak • Blocking Network Analysis • Heat Testing Additionally, both predicate and modified devices have a successful biocompatibility track record, as demonstrated by ISO 10993 testing and by their history of use in previously cleared devices. The following quality assurance measures were applied to the development of the device: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Performance testing (Verification) • Safety testing (Verification) • Simulated use testing (Validation) Summary of Clinical Tests: The subject of this premarket submission, the 48CH Head Coil, did not require clinical studies to support substantial equivalence. Sample clinical images have been included in this submission.

	Substantial Equivalence Conclusion: The indications for use of the proposed device are comparable to the claimed predicate device. The 48CH Head Coil employs equivalent technology to the claimed predicate device. Additionally, the results from the above non-clinical tests demonstrate that the device performs as intended. Thus, the 48CH Head Coil is substantially equivalent to the predicate device to which it has been compared.
Conclusion:	GE Healthcare considers the 48CH Head Coil to be as safe, as effective, and performance is substantially equivalent to the predicate devices.