GE Healthcare Coils (USA Instruments, Inc.)
Veronica Meridith
Regulatory Affairs Leader
1515 Danner Drive
Aurora, Ohio 44202

April 12, 2018

Re: K180666
Trade/Device Name: 48CH Head Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: March 12, 2018
Received: March 14, 2018

Dear Veronica Meridith:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180666

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K180666

510(k) Summary

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

Date:	March 12, 2018
Submitter:	GE Healthcare Coils (USA Instruments, Inc.) 1515 Danner Drive Aurora, OH 44202 USA
Primary Contact Person:	Veronica Meridith Regulatory Affairs Leader GE Healthcare Phone: 262-955-5427 Fax: 414-908-9585
Secondary Contact Person:	Andrew Menden Regulatory Affairs Manager GE Healthcare Phone: 262-521-6223 Fax: 414-908-9585
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):	48CH Head Coil (K163205)
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. 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:	The intended use statements are identical.
Comparison of Technological Characteristics:	The 48CH Head Coil employs the same fundamental scientific technology as its predicate device. Coil Design: The 48CH Head Coil design is the same as the predicate device but implements a design change to the decoupling circuit. Operating Principles: The 48CH Head Coil operates on the same principles as the predicate device. Materials: The 48CH Head Coil uses the same materials as the predicate device. Safety and Performance Testing: The 48CH Head Coil complies with the same safety and performance testing as the predicate device. 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 the same 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 • MS6-2008 • Maximum B1 Peak • Blocking Network Analysis • Surface Temperature Testing The predicate and modified devices use the same patient contact materials and comply with ISO 10993 biocompatibility testing. 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. Substantial Equivalence Conclusion: The indications for use of the proposed device are identical 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 and effective, and performs in a substantially equivalent manner to the predicate device.