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

October 12, 2018

Re: K182504
Trade/Device Name: 3.0T Air MP M, 3.0T Air MP L
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: September 10, 2018
Received: September 12, 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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; 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 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)*

K182504

Device Name
3.0T AIR MP M

Indications for Use *(Describe)*

The 3.0T AIR MP M is a receive only RF coil designed for use with GE 3.0T MRI systems to produce diagnostic images on general human anatomy including extremities. The nucleus detected 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K182504

Device Name
3.0T AIR MP L

Indications for Use *(Describe)*

The 3.0T AIR MP L is a receive only RF coil designed for use with GE 3.0T MRI systems to produce diagnostic images on general human anatomy including extremities. The nucleus detected 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)

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510(k) Summary

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

Date:	September 07, 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

	3.0T AIR MP M	3.0T AIR MP L
Device Trade Name:	3.0T AIR MP M	3.0T AIR MP L
Common/Usual Name:	Coil, Magnetic Resonance, Specialty	Coil, Magnetic Resonance, Specialty
Classification Names:	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000
Product Code:	MOS	MOS
Predicate Device(s):	3.0T Anterior Array (K172695)	3.0T Anterior Array (K172695)
Device Description:	The 3.0T AIR MP M is a receive-only coil designed to provide optimum signal-to noise and uniform coverage of general human anatomy including extremities and are designed for use with GE 3.0T MRI Systems. This is a 20 element coils tuned to image proton nuclei. Each coil element has an integrated preamplifier to improve image quality. The 3.0T AIR MP M is provided with P-connectors. The coil has a soft material to conform to the patient's anatomy and maximize patient comfort. Due to the flexibility of the coils, a coil holder may be used to assist in securing the coil in place.	The 3.0T AIR MP L is a receive-only coil designed to provide optimum signal-to noise and uniform coverage of general human anatomy including extremities and are designed for use with GE 3.0T MRI Systems. This is a 21 element coils tuned to image proton nuclei. Each coil element has an integrated preamplifier to improve image quality. The 3.0T AIR MP L is provided with P-connectors. The coil has a soft material to conform to the patient's anatomy and maximize patient comfort. Due to the flexibility of the coils, a coil holder may be used to assist in securing the coil in place.
Intended Use:	The 3.0T AIR MP M is a receive-only RF coil designed for use with GE 3.0T MRI systems to produce diagnostic images of general human anatomy including extremities. The nucleus detected is hydrogen	The 3.0T AIR MP L is a receive-only RF coil designed for use with GE 3.0T MRI systems to produce diagnostic images of general human anatomy including extremities. The nucleus detected is hydrogen.
Comparison of	Both the 3.0T AIR MP M and the predicate	Both the 3.0T AIR MP M and the predicate

Intended Use:	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 3.0T AIR MP M and the predicate device are indicated for the same patient population, and for the same clinical setting. The proposed Indications for use are simplified to reflect current coil intent, similar to the Siemens Contour 24 coil K173446, 510k cleared 11/17/2017. The Siemens Contour 24 coil Indications for Use is: *"The Contour 24 is intended for use with Siemens 3.0T MR systems to produce diagnostic images of general human anatomy that can be interpreted by a trained physician."* Therefore, GE Healthcare believes that the 3.0T AIR MP M 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.	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 3.0T AIR MP M and the predicate device are indicated for the same patient population, and for the same clinical setting. The proposed Indications for use are simplified to reflect current coil intent, similar to the Siemens Contour 24 coil K173446, 510k cleared 11/17/2017. The Siemens Contour 24 coil Indications for Use is: *"The Contour 24 is intended for use with Siemens 3.0T MR systems to produce diagnostic images of general human anatomy that can be interpreted by a trained physician."* Therefore, GE Healthcare believes that the 3.0T AIR MP M 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 3.0T AIR MP M employs the same fundamental scientific technology as its predicate device. **Coil Design:** The most notable technological differences between the 3.0T AIR MP M and the	Overall, the 3.0T AIR MP L employs the same fundamental scientific technology as its predicate device. **Coil Design:** The most notable technological differences between the 3.0T AIR MP L and the

	predicate AIR Anterior Array is that 1) The 3.0T AIR MP M contains 20 elements as compared to the predicate's 30 elements and 2) The 3.0T AIR MP M is used on GE 3.0T MRI as compared to the predicate's GE 3.0T MRI systems	predicate AIR Anterior Array is that 1) The 3.0T AIR MP L contains 21 elements as compared to the predicate's 30 elements and 2) The 3.0T AIR MP L is used on GE 3.0T MRI as compared to the predicate's GE 3.0T MRI systems
	Operating Principles: The 3.0T MP M and 3.0T AIR MP L both operate on the same principles as the predicate devices. **Materials:** The 3.0T AIR MP M and 3.0T AIR MP L electrical elements and associated circuitry are supported throughout the coil by flame rated V2 co-polyester injection mold enclosure and V0 equivalent flame rated enclosures. Both coils and the predicate device are certified to AAMI/ANSI ES60601-1, which includes flammability requirements. **Safety and Performance Testing:** The 3.0T MP M and 3.0T AIR MP L and the predicate devices comply 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 • NEMA MS 6 • NEMA MS 9 • Maximum B1 peak	

	• Network blocking 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 devices: • 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 subjects of this premarket submission, the 3.0T AIR MP M and 3.0T AIR MP L, do 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 devices are comparable to the claimed predicate devices. The 3.0T AIR MP M and 3.0T AIR MP L employs equivalent technology to the claimed predicate devices. Additionally, the results from the above non-clinical tests demonstrate that the devices perform as intended. Thus, the 3.0T AIR MP M and 3.0T AIR MP L are substantially equivalent to the predicate devices to which they have been compared.
Conclusion:	GE Healthcare considers the 3.0T AIR MP M and 3.0T AIR MP L to be as safe, as effective, and performance is substantially equivalent to the predicate devices.