GE Healthcare Coils (USA Instruments, Inc.)
Mary Mayka
Regulatory Affairs Manager
1515 Danner Drive
Aurora, Ohio 44202

December 8, 2017

Re: K172695
Trade/Device Name: AIR Anterior Array, AIR Posterior Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: November 3, 2017
Received: November 6, 2017

Dear Mary Mayka:

This letter corrects our substantially equivalent letter of November 22, 2017.

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)*

K172695

Device Name
AIR Anterior Array

Indications for Use *(Describe)*

The AIR Anterior Array is a receive-only RF coil designed for use with GE 3.0T MRI Systems. When used with other coils, the indications for use include chest, cardiac, abdomen, torso, pelvis, prostate, hips, peripheral vascular and long bone imaging. 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:

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Paperwork Reduction Act (PRA) Staff
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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)*

Device Name
AIR Posterior Array

Indications for Use *(Describe)*
The AIR Posterior Array is a receive-only RF coil designed for use with GE 3.0T MRI Systems. The indications for use include spine. When used with other coils, the indications for use also include abdomen, torso, pelvis, prostate, cardiac, hips, and long bone imaging. 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 05, 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:	James D. McMahon Regulatory Affairs Director GE Healthcare Phone: 508-382-2858 Fax: 262-364-2785

	AIR Anterior Array	AIR Posterior Array
Device Trade Name:	AIR Anterior Array	AIR Posterior Array
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 AA (K143345)	TDI Posterior Array (K143345)
Device Description:	The AIR Anterior Array is a receive-only coil designed to provide optimum signal-to noise ratio and uniform coverage of the chest, cardiac, abdomen, torso, pelvis, prostate, hips, peripheral vascular and long bone. The AIR Anterior Array contains 30 elements and the housing of the AIR Anterior Array is made of a soft, pliable material that conforms to the patient's anatomy. The coil is padded with a soft material designed to maximize patient comfort.	The AIR Posterior Array is a receive-only coil designed to provide optimum signal-to noise ratio and uniform coverage of the spine, abdomen, torso, pelvis, prostate, cardiac, hips and long bone. The AIR Posterior Array contains 60 elements and is embedded within the patient table of the MR System.
Intended Use:	The AIR Anterior Array is a receive-only RF coil designed for use with GE 3.0T MRI systems. When used with other coils, the indications for use include chest, cardiac, abdomen, torso, pelvis, prostate, hips, peripheral vascular, and long bone imaging. The nucleus detected is hydrogen.	The AIR Posterior Array is a receive-only RF coil designed for use with GE 3.0T MRI Systems. The indications for use include spine. When used with other coils, the indications for use also include abdomen, torso, pelvis, prostate, cardiac, hips, and long bone imaging. The nucleus detected is hydrogen.

	AIR Anterior Array	AIR Posterior Array
Comparison of Intended Use:	Both the AIR Anterior Array 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 AIR Anterior Array and the predicate device are indicated for the same patient population, and for the same clinical setting. The predicate device, the 3.0T AA, is one coil as part of the TDI Coil Suite and covers brachial-plexus, pelvis, hips, prostate, abdominal, cardiac, lower extremities, blood, vessels, or long bone anatomies. Therefore, GE Healthcare believes that the AIR Anterior Array 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.	Both the AIR Posterior Array 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 AIR Posterior Array and the predicate device are indicated for the same patient population, and for the same clinical setting. The predicate device, the 3.0T AA, is one coil as part of the TDI Coil Suite and covers pelvis, hips, prostate, abdominal, cardiac, lower extremities, or long bone anatomies. Therefore, GE Healthcare believes that the AIR Posterior Array 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 AIR Anterior Array employs the same fundamental scientific technology as its predicate device. **Coil Design:** The most notable technological differences between the AIR Anterior Array and the predicate 3.0T AA is that	Overall, the AIR Posterior Array employs the same fundamental scientific technology as its predicate device. **Coil Design:** The most notable technological difference between the AIR Posterior Array and the predicate TDI Posterior Array is that the AIR

	AIR Anterior Array	AIR Posterior Array
	1) the AIR Anterior Array contains 30 elements as compared to the predicate's 16 elements and 2) The housing of the AIR Anterior Array is made of a soft, pliable material that conforms to the patient's anatomy as compared to the predicate's semi-rigid construction.	Anterior Array contains 60 elements as compared to the predicate's 32 elements.
	Operating Principles: The AIR Anterior Array and AIR Posterior Array both operate on the same principles as the predicate devices. **Materials:** The AIR Anterior Array and AIR Posterior Array and the predicate devices use flame retardant materials. **Safety and Performance Testing:** The AIR Anterior Array and AIR Posterior Array 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 • MS 6-2008 • MS 9-2008 • 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 AIR Anterior Array and AIR Posterior Array, 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 AIR Anterior Array and AIR Posterior Array 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 AIR Anterior Array and AIR Posterior Array are substantially equivalent to the predicate devices to which they have been compared.
Conclusion:	GE Healthcare considers the AIR Anterior Array and AIR Posterior Array to be as safe, as effective, and performance is substantially equivalent to the predicate devices.