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

October 19, 2018

Re: K182590
Trade/Device Name: 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, 1.5T 30ch AIR AA
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: September 19, 2018
Received: September 20, 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,

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)*
K182590

Device Name
1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, 1.5T 30ch AIR AA

Indications for Use *(Describe)*
The 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA are receive only RF coils designed for use with GE 1.5T 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.

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K182590

**GE Healthcare**

510(k) Premarket Notification Submission

## 510(k) Summary

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

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| Date: | Sept 19, 2018 |
| Submitter: | GE Healthcare Coils (USA Instruments, Inc.)<br>1515 Danner Drive<br>Aurora, OH 44202<br>USA |
| Primary Contact Person: | Veronica Meridith<br>Regulatory Affairs Leader<br>GE Healthcare<br>Phone: 262-955-5427<br>Fax: 414-908-9585 |
| Secondary Contact Person: | Andrew Menden<br>Regulatory Affairs Manager<br>GE Healthcare<br>Phone: 262-521-6223<br>Fax: 414-908-9585 |

**GE Healthcare**
510(k) Premarket Notification Submission

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| Device Trade Name: | 1.5T AIR MP M<br>1.5T AIR MP L<br>1.5T 16ch AIR AA<br>1.5T 30ch AIR AA |
| Common/Usual Name: | Coil, Magnetic Resonance, Specialty |
| Classification Names: | Magnetic Resonance Diagnostic Device per 21 CFR 892.1000 |
| Product Code: | MOS |
| Predicate Device(s): | 3.0T Anterior Array (K172695) |
| Device Description: | The 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA and 1.5T 30ch AIR AA are receive-only coils designed to provide optimum signal-to noise ratio and uniform coverage of general human anatomy including extremities and are designed for use with GE 1.5T MRI Systems. These are 20, 21, 16, and 30 element coils tuned to image proton nuclei. Each coil element has an integrated preamplifier to improve image quality. These coils are provided with P-connectors. The coils have 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 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA are receive only RF coils designed for use with GE 1.5T MRI systems to produce diagnostic images on general human anatomy including extremities. The nucleus detected is hydrogen. |
| Comparison of Intended Use: | The 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA 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 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA and the predicate device are indicated for the same patient population, and for the same clinical setting.<br><br>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.*"<br><br>Therefore, GE Healthcare believes that the 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA 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. |

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| Comparison of Technological Characteristics: | The 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA and the predicate device share many common technological characteristics. Details can be found in the table below, which shows the high-level device description for all four new coils as compared to the predicate device:<br><br>The most notable technological differences between the new coils and the predicate device is that the new devices contain (respectively):<br><br>20 elements<br>21 elements<br>16 elements<br>30 elements<br>Predicate: 30 elements<br>The predicate is used on GE 3.0T MRI Systems while the new devices are for use with GE 1.5T MRI systems.<br><br>These technological differences do not raise any different questions of safety and effectiveness. All devices must address questions of whether they provide an adequate level of image quality appropriate for diagnostic use. The performance data described in this submission include results of both bench testing and clinical testing that show the image quality performance of the 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA compared to the predicate device.<br><br>**Operating Principles:** The 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA operate on the same principles as the predicate devices.<br><br>**Materials:** The 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA 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.<br>Both coils and the predicate device are certified to AAMI/ANSI ES60601-1, which includes flammability requirements.<br>**Safety and Performance Testing:** The 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA and the predicate devices comply with the same safety and performance testing (see Determination of Substantial Equivalence, below). |

**GE Healthcare**
510(k) Premarket Notification Submission

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| Determination of Substantial Equivalence: | Summary of Non-Clinical Tests:<br>The predicate and modified devices have been subject to similar risk management testing to demonstrate substantial equivalence of safety and performance. Testing included:<br>• AAMI/ANSI ES60601-1<br>• IEC 60601-1-2<br>• IEC 60601-2-33<br>• NEMA MS 6<br>• NEMA MS 9<br>• Maximum B1 peak<br>• Network blocking analysis<br>• Heat Testing<br>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.<br><br>The following quality assurance measures were applied to the development of the devices:<br>• Risk Analysis<br>• Requirements Reviews<br>• Design Reviews<br>• Testing on unit level (Module verification)<br>• Integration testing (System verification)<br>• Performance testing (Verification)<br>• Safety testing (Verification)<br>• Simulated use testing (Validation)<br><br>Summary of Clinical Tests:<br>The subjects of this premarket submission, the 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA, do not require clinical studies to support substantial equivalence. Sample clinical images have been included in this submission.<br>Substantial Equivalence Conclusion:<br>The indications for use of the proposed devices are comparable to the claimed predicate devices. The 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA 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 1.5T AIR MP M and 1.5T AIR MP L are substantially equivalent to the predicate devices to which they have been compared. |
| Conclusion: | GE Healthcare considers the 1.5T AIR MP M, 1.5T AIR MP L, 1.5T 16ch AIR AA, and 1.5T 30ch AIR AA to be as safe, as effective, and performance is substantially equivalent to the predicate devices. |