January 3, 2023

GE Healthcare Coils (USA Instruments, Inc.)
% Lauren Ross
Regulatory Affairs Leader
1515 Danner Drive
Aurora, Ohio 44202

Re: K223378
Trade/Device Name: 3.0T 16ch AIR AA
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: November 4, 2022
Received: November 7, 2022

Dear Lauren Ross:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223378

Device Name
3.0T 16ch AIR AA

Indications for Use *(Describe)*
The 3.0T 16ch AIR AA 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.

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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510(k) Summary

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

Date: January 3, 2022

Submitter:
GE Healthcare Coils (USA Instruments, Inc.)
1515 Danner Drive
Aurora, OH 44202
USA

Primary Contact Person:
Lauren Ross
Regulatory Affairs Leader
GE Healthcare
Phone: 262-399-5721

Secondary Contact Person:
Andrew Menden
Regulatory Affairs Leader
GE Healthcare
Phone: 262-399-5721

Device Trade Name: 3.0T 16ch AIR AA

Common/Usual Name: Coil, Magnetic Resonance, Specialty

Product Classification:

- **Classification Name:** Magnetic Resonance Diagnostic Device
- **Regulation Number:** 21 CFR 892.1000
- **Product Code:** MOS

Predicate Device: 1.5T 16ch AIR AA (K182590)

Device Description:

The 3.0T 16ch AIR AA is a receive-only coil designed to provide optimum signal-to noise and uniform coverage of general human anatomy including extremities. The coil has 16 elements tuned to image proton nuclei. Each coil element has an integrated preamplifier to improve image quality. The 3.0T 16ch AIR AA is provided with a P-connector that is compatible with GE Healthcare 3.0T MR systems. The coils have a soft material to conforms to the patient's anatomy and maximize patient comfort.

Indications Use:

The 3.0T 16ch AIR AA 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 the Indications for Use:

Both the 3.0T 16ch 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 3.0T 16ch AIR AA and the predicate device are indicated for the same patient population, and for the same clinical setting.

Therefore, GE Healthcare believes that the 3.0T 16ch 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.

Comparison of Technological Characteristics:

The most notable technological difference between the 3.0T 16ch AIR AA and the predicate device is that the 3.0T 16ch AIR AA is tuned to the frequency for imaging hydrogen nuclei (protons) at 3.0T, while the predicate device is intended for 1.5T. This technological difference does not raise any different questions of safety and effectiveness. Both devices must address questions of whether they provide appropriate mitigations for electrical, mechanical, thermal, and biocompatibility risks, and provide an adequate level of image quality for diagnostic use.

Summary of Non-Clinical Tests:

The 3.0T 16ch AIR AA has undergone the following testing:

- Image Signal-to-Noise Ratio (SNR) in accordance with NEMA MS-9
- Image Uniformity in accordance with NEMA MS-9
- Surface heating in accordance with NEMA MS-14
- Inspection of decoupling circuitry
- EMC testing for immunity from electrostatic discharge in accordance with applicable portions of IEC 60601-1-2
- General electrical and mechanical safety in accordance with applicable portions of AAMI/ANSI ES 60601-1 and IEC 60601-2-33
- Biocompatibility assessment in accordance with the ISO 10993 series of standards

The results of the non-clinical tests satisfy the performance criteria defined in the FDA guidance document *Magnetic Resonance (MR) Receive-only Coil – Performance Criteria for Safety and Performance Based Pathway*.

Summary of Clinical Tests:

In accordance with the FDA guidance document *Magnetic Resonance (MR) Receive-only Coil – Performance Criteria for Safety and Performance Based Pathway*, sample clinical images have been obtained with the 3.0T 16ch AIR AA from various anatomies and using various pulse sequences. The sample images have been assessed by a U.S. Board Certified Radiologist and determined to be of diagnostic quality.

Substantial Equivalence Conclusion:

The indications for use of the proposed devices are comparable to the claimed predicate devices. The 3.0T 16ch 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 3.0T 16ch AIR AA are substantially equivalent to the predicate device to which they have been compared.

Conclusion:

Based on the results of the non-clinical and clinical testing, GE Healthcare concludes that the 3.0T 16ch AIR AA is as safe, as effective, and performs as well as or better than the predicate device. The 3.0T 16ch AIR AA also meets the performance criteria outlined in the *Magnetic Resonance (MR) Receive-only Coil – Performance Criteria for Safety and Performance Based Pathway* guidance.