January 23, 2026

Ge Healthcare Coils (Usa Instruments, Inc.)
Sahra Nur
Lead Specialist, Regulatory Affairs - MR
1515 Danner Dr.
Aurora, Ohio 44202

Re: K253738
Trade/Device Name: 3.0T AIR 32CH HNA
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: November 24, 2025
Received: November 24, 2025

Dear Sahra Nur:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253738

Please provide the device trade name(s).

3.0T AIR 32CH HNA

Please provide your Indications for Use below.

The 3.0T AIR™ 32CH HNA is a receive-only RF Coil designed for use with GE HealthCare 3.0T MRI systems. The coil is indicated for high-resolution magnetic resonance imaging (MRI) of the head and brain. When used with a Posterior Array in the MRI System patient table it also includes neck, cervical spine, neurovascular structures, upper thoracic spine, and brachial plexus imaging. The nucleus detected is hydrogen.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K253738

510(k) Summary

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

Date:	January 22, 2026
Submitter:	GE Healthcare Coils (USA Instruments, Inc.) 1515 Danner Drive Aurora, OH 44202 USA
Primary Contact Person:	Sahra Nur Lead Specialist, Regulatory Affairs GE Healthcare Phone: 416-770-4678
Secondary Contact Person:	Andrew Menden Sr. Director, Regulatory Affairs GE Healthcare Phone: 262-308-5719
Device Trade Name:	**3.0T AIR 32CH HNA**
Common/Usual Name:	Coil, Magnetic Resonance, Specialty
Product Code:	MOS
Predicate Device:	48CH Head Coil (K180666)

Device Description:

The 3.0T AIR 32CH HNA is a receive-only radio frequency coil engineered to deliver optimal signal-to-noise ratio, uniform anatomical coverage, and high acceleration capabilities, including multiband imaging. It is intended for high-resolution magnetic resonance imaging (MRI) of the head and brain. When used in conjunction with the Posterior Array in the MRI system's patient table, it also supports imaging of the neck, cervical spine, neurovascular structures, upper thoracic spine, and brachial plexus. The nucleus detected is hydrogen. This coil is compatible with GE HealthCare 3.0T MRI systems.

The 3.0T AIR 32CH HNA is designed to be used by a Registered MRI Technologist in a hospital or clinical setting. The Registered MRI Technologist will operate the scanner from the control room. If the patient is claustrophobic another MRI Technologist or clinical staff member may stay in the magnet room with the patient.

Indications for Use:

The 3.0T AIR™ 32CH HNA is a receive-only RF Coil designed for use with GE HealthCare 3.0T MRI systems. The coil is indicated for high-resolution magnetic resonance imaging (MRI) of the head and brain. When used with a Posterior Array in the MRI System patient table it also includes neck, cervical spine, neurovascular structures, upper thoracic spine, and brachial plexus imaging. The nucleus detected is hydrogen.

Comparison of the Indications for Use:

Both the 3.0T AIR 32CH HNA 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 AIR 32CH HNA 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 AIR 32CH HNA 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 significant technological difference between the 3.0T AIR 32CH HNA coil and the predicate device, the 3.0T 48-channel Head Coil, is the inclusion of an additional AIR Neck-Chest Unit in the 3.0T AIR 32CH HNA.

These technological differences do not raise any different questions of safety and effectiveness. Both 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 new device compared to the predicate device.

Summary of Non-Clinical Tests:

The 3.0T AIR 32CH HNA 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 AIR 32CH HNA 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 AIR 32CH HNA 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 32CH HNA 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 AIR 32CH HNA is as safe, as effective, and performs as well as or better than the predicate device. The 3.0T AIR 32CH HNA also meets the performance criteria outlined in the Magnetic Resonance (MR) Receive-only Coil – Performance Criteria for Safety and Performance Based Pathway guidance.