December 23, 2025

GE Medical Systems, LLC
Andrew Turner
Regulatory Affairs Leader
3200 N. Grandview Blvd.
Waukesha, Wisconsin 53188

Re: K252379
Trade/Device Name: AIR Recon DL
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: December 5, 2025
Received: December 8, 2025

Dear Andrew Turner:

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.	K252379

Please provide the device trade name(s).

AIR Recon DL

Please provide your Indications for Use below.

AIR Recon DL is a deep learning based reconstruction technique that is available for use on GE HealthCare 1.5T, 3.0T, and 7.0T MR systems. AIR Recon DL reduces noise and ringing (truncation artifacts) in MR images, which can be used to reduce scan time and improve image quality. AIR Recon DL is intended for use with all anatomies, and for patients of all ages. Depending on the anatomy of interest being imaged, contrast agents may be used.

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

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

510(k) Summary
In accordance with 21 CFR 807.92, the following summary of information is provided:

Date	December 19, 2025
Submitter	GE Medical Systems, LLC 3200 N. Grandview Blvd. Waukesha, WI 53188
Primary Contact	Andrew Turner Regulatory Affairs Leader 484-630-7798 Andrew.Turner@gehealthcare.com
Secondary Contact	Glen Sabin Regulatory Affairs Director 262-894-4968 Glen.Sabin@gehealthcare.com
Device Trade Name	AIR Recon DL
Common/Usual Name	MR System
Classification Name	Magnetic Resonance Diagnostic Device
Regulation Number	21 CFR 892.1000
Product Code	LNH
Predicate Device(s)	AIR Recon DL (K213717)

Device Description
AIR Recon DL is a software feature intended for use with GE HealthCare MR systems. It is a deep learning-based reconstruction technique that removes noise and ringing (truncation) artifacts from MR images. AIR Recon DL is an optional feature that is integrated into the MR system software and activated through purchasable software option keys. AIR Recon DL has been previously cleared for use with 2D Cartesian, 3D Cartesian, and PROPELLER imaging sequences.

The proposed device is a modified version of AIR Recon DL that includes a new deep-learning phase correction algorithm for applications that create multiple intermediate images and combine them, such as Diffusion Weighted Imaging where multiple NEX images are collected and combined. This enhancement is an optional feature that is integrated into the MR system software and activated through an additional purchasable software option key (separate from the software option keys of the predicate device).

Indications for Use
AIR Recon DL is a deep learning-based reconstruction technique that is available for use on GE HealthCare 1.5T, 3.0T, and 7.0T MR systems. AIR Recon DL reduces noise and ringing (truncation artifacts) in MR images, which can be used to reduce scan time and improve image quality. AIR Recon DL is intended for use with all anatomies, and for patients of all ages. Depending on the anatomy of interest being imaged, contrast agents may be used.

Comparison of Technological Characteristics

The proposed AIR Recon DL feature that is the subject of this 510(k) is a modification to the earlier version of the feature described in the predicate device submission, K213717. The feature has been modified to include a new DL Phase Correction (DLPC) model and a new PC Compatible AIR Recon DL (PC-ARDL) model for use with applications that create multiple intermediate images and combine them, such as Diffusion Weighted Imaging. Working together, the DLPC and PC-ARDL models are also known as AIR Recon DL with Phase Correction.

Summary of Nonclinical Testing

The new DLPC and PC-ARDL models have undergone phantom testing to evaluate the feature and its impact on image quality. The DLPC model testing included the accuracy of phase correction and the impact on the noise floor. The PC-ARDL model was tested for SNR, sharpness, and low contrast detectability.

The nonclinical testing demonstrates that the DLPC model provides more accurate phase correction and can effectively reduce signal bias compared to conventional phase correction methods. For diffusion applications, the DLPC model can reduce the noise floor and bias of ADC quantification in low SNR scenarios. The PC-ARDL testing demonstrates that the feature can improve SNR and image sharpness without changing contrast. The PC-ARDL model can also help reduce scan time while maintaining SNR. The nonclinical testing passed the defined acceptance criteria and did not identify any adverse impacts to image quality or other concerns related to safety and performance.

Summary of Clinical Testing

<u>In-Vivo performance testing</u>

The DLPC and the PC-ARDL models have undergone bench testing with in-vivo data to evaluate the feature and its impact on image quality relative to the predicate device. Testing was done to measure ADC accuracy and low contrast detectability to evaluate phase correction performance.

The accuracy of ADC measurements was obtained from diffusion images at multiple b-values. Diffusion weighted brain images were acquired at 1.5T with b-values = 50, 400, 800, 1200 s/mm^2. ADC maps were generated from (b50, b400), (b50, b800), (b50, b1200) diffusion-weighted images with the combination of DLPC and PC-ARDL and separately with the predicate device. Average ADC values were measured from regions of interest in the lateral ventricles where isotropic Gaussian diffusion is expected to provide b-value independent ADC values. DLPC with PC-ARDL did not show significant differences in ADC values measured with different b-values while the predicate device has statistically significant reductions in ADC as the maximum b-value increased. DL PC-based complex averaging was found to reduce the noise floor, resulting in a log-linear signal decay that provides accurate and unbiased ADC values at all b-values tested.

Low-contrast detectability was tested by measuring the intensity of small synthetic objects inserted in the raw data prior to reconstruction. Inserts of varying sizes and intensities, chosen to be challenging to detect, were inserted in the raw data obtained from 4 diffusion weighted brain scans. The contrast ratio and contrast-to-noise ratio for each of the inserts were measured and paired t-tests were conducted between DLPC (with PC-ARDL) and the predicate device. While the contrast ratios remained relatively unchanged with insert size or intensity, the contrast to noise ratio showed a significant improvement with the addition of DLPC and PC-ARDL. We conclude from this test that AIR Recon DL with Phase Correction is not adversely impacting the retention of low contrast features.

Quantitative Post Processing

To test the repeatability of AIR Recon DL with Phase Correction for ADC measurement, volunteer scanning was performed simulating routine clinical workflows. A total of 6 volunteers were recruited. Two volunteers were scanned on a 1.5T SIGNA Artist scanner, and 4 volunteers were scanned on a 3T SIGNA Architect scanner. Scanned anatomical regions included the brain, spine, abdomen, pelvis, and breast. Each sequence was repeated 4 times and retrospectively reconstructed to generate images with product reconstruction and AIR Recon DL with Phase Correction (with DLPC and PC-ARDL models) respectively. ADC maps were generated on the product and AIR Recon DL with Phase Correction images. Regions of interests were placed on images to compare repeatability across multiple acquisitions. While there were cases that were influenced by scan-to-scan variability caused by motion or flow, overall, the repeatability was found to be similar between the phase correction methods. The coefficient of variability for the ADC values generated with the product reconstruction closely matched those generated with AIR Recon DL with Phase Correction.

To compare the effectiveness of different phase correction methods, the real and imaginary images of a complex image after phase correction were shown for both conventional images and DLPC images. In an ideal scenario, after phase correction, the signal of a complex image should all be in the real channel, and the imaginary channel should be noise only. It was shown that when conventional method was used, residual signal was still present in the imaginary channel of each individual NEX image after phase correction, which would cause signal loss and inaccurate ADC maps. For DLPC, it was observed that all the signal was in the real channel, and the imaginary channel contained noise only, as expected.

The quantitative measurements in this repeatability study showed that DLPC is outperforming the conventional phase correction method in terms of accurately moving all the true MR signals into the real channel of a complex image and leaving the imaginary channel with noise only.

Clinical Image Quality Study

An assessment was conducted with a U.S. Board Certified Radiologist to evaluate the diagnostic quality of images acquired and reconstructed with AIR Recon DL with Phase Correction. The

study included 34 datasets of previously acquired de-identified cases of various anatomies including the breast (6 datasets), liver (5 datasets), brain (5 datasets), spine (3 datasets) and pelvis (15 datasets). These datasets included pathological features such as prostate cancer of varying severity, hepatocellular carcinoma, septal fibrosis, and fibroadenoma. After review and assessment, it was concluded by the radiologist that AIR Recon DL with Phase Correction produces images of excellent diagnostic quality, delivering overall exceptional image quality across all organ systems. Even in most challenging situations such as post-surgical changes, or implants, the image quality remains excellent without loss of diagnostic quality.

Clinical Publications

The following peer reviewed studies provide further quantitative and qualitative evidence of the ability of AIR Recon DL with Phase Correction to improve image quality across various clinical applications.

[1] Wang X, Litwiller D, Guidon A, Lan P, Sprenger T, Robust Complex Signal Averaging for Diffusion Weighted Imaging, ISMRM & ISMRT Annual Meeting & Exhibition, 2023, Toronto, ON, Canada
[2] Shen D, Wang X, Lan P, Sun W, Deep Learning based Phase Correction with Noise and Artifacts Removal for MERGE, ISMRM & ISMRT Annual Meeting & Exhibition, 2024, Singapore
[3] Wang X, Lan P, Guidon A, DL-based Phase Correction Enables Robust Real Diffusion-Weighted MRI with Increased Diffusion Contrast, ISMRM & ISMRT Annual Meeting & Exhibition, 2024, Singapore
[4] Lan P, Wang X, Guidon A, Reduced Noise and Motion Artifacts for MUSE Reconstruction using Deep Learning-based Phase Correction, ISMRM & ISMRT Annual Meeting & Exhibition, 2024, Singapore
[5] Brunsing R, Besser A, Guidon A, Wang X, Lan P, Deep-learning-based phase correction during reconstruction of high-resolution, multi-shot reduced-FOV pancreatic DWI, ISMRM & ISMRT Annual Meeting & Exhibition, 2024, Singapore
[6] S Huang, X Wang, M Medved, C Follante, Y Stickle, A Yousuf, R Englemann, F Robb, A Guidon, G Lee, A Oto, Impact of Deep Learning denoising and ultra-high density coil array on prostate diffusion imaging, ISMRM, 2025, Hawaii
[7] S Zhang, R Zhao, X Wang, P Lan, P Martin, A Guidon, D Martin, N Gupta. Deep learning-based phase correction improves DWI for bladder cancer imaging, ISMRM Diffusion Workshop, 2025, Tokayo, Japan
[8] Yang B, Wang X, Petty C, Guidon A, Lebel RM, Banerjee S, Song A, Submillimeter Isotropic Whole Brain DTI at 3T with 2D Multi-band Multi-shot EPI Acquisition and Deep Learning Reconstruction, ISMRM & ISMRT Annual Meeting & Exhibition, 2024, Singapore
[9] Wang X, Lan P, Wang K, Zhu A, Nastaren A and Guidon A. Deep Learning based Phase Correction and Denoising for Accurate ADC Quantification. ISMRM, 2025, Hawaii
[10] Lan P, Wang X, Guidon A. Improved Brachial Plexus and C-Spine DTI using Deep Learning-based Phase Correction. ISMRM, 2025, Hawaii
[11] Lee E, Li C, Lan P, Wang X, Guidon A, Lin C, Deep Learning Reconstruction to Pelvis Multi-Shot DWI Improved Image Quality with Less Image Distortion: A Preliminary Study, ISMRM & ISMRT Annual Meeting & Exhibition, 2023, Toronto, ON, Canada

[12] Chien N, Yeh CY, Chen YC, Chang YC, Li CW, Lin CY, Lan P, Wang X, Guidon A, Liu KL, Deep Learning Based Reconstruction for Multi-shot DWI of the Breast: A Preliminary Study, ISMRM & ISMRT Annual Meeting & Exhibition, 2023, Toronto, ON, Canada
[13] Lan P, Wang X, Scotti A, Jayapal P, Wang P, Guidon A, Loening AM, Improved Image Quality with Deep Learning-Based Image Reconstruction for Multi-shot Diffusion-Weighted Imaging of the Prostate, ISMRM & ISMRT Annual Meeting & Exhibition, 2023, Toronto, ON, Canada
[14] E Milshteyn, S Ghosh, X Wang, P Lan, A Analysis of Deep Learning-based Phase Correction Applied to Single-Shot rFOV Diffusion Images of the Prostate at 1.5T, ISMRM 2025, Hawaii
[15] Chien N, Cho YH, Chen YC, Yeh CY, Chang YC, Lee CW, Lin CY, Lan P, Wang X, Guidon A, Liu KL, Deep Learning Based Reconstruction for Multi-shot DWI of the Breast: Comparison of Quantitative ADC and Distortion, ISMRM & ISMRT Annual Meeting & Exhibition, 2024, Singapore
[16] R Khadir, S Gallo-Bernal, V Pena Trujillo, EJ Zucker, A Pourvaziri, S Fazio Ferraciolli, E Milshteyn, X Wang, P Lan, A Guidon, T Victoria,M Gee, Deep Learning Phase-Corrected Reconstruction in Pediatric Diffusion-Weighted Abdominal MRI: a comparative study, SPR 2025, Hawaii
[17] Chien N, Cho YH, Wang MY, Tsai LW, Yeh CY, Li CW, Lan P, Wang X, Liu KL, Chang YC, Deep learning based multi-shot breast diffusion MRI: Improving imaging quality and reduced distortion, European Journal of Radiology, 2025
[18] Michael A. Boss, Dariya Malyarenko, Savannah Partridge, Nancy Obuchowski, Amita Shukla-Dave, Jessica M. Winfield, Clifton D. Fuller, Kevin Miller, Virendra Mishra, Michael Ohliger, Lisa J. Wilmes, Raj Attariwala, Trevor Andrews, Nandita M. deSouza, Daniel J. Margolis, Thomas L. Chenevert, The QIBA Profile for Diffusion-Weighted MRI: Apparent Diffusion Coefficient as a Quantitative Imaging Biomarker, *Radiology:* Volume 313: Number 1—October 2024

Conclusion Drawn from Performance Testing

The nonclinical and clinical testing demonstrated that AIR Recon DL with Phase Correction satisfies the product claims that it can provide more accurate estimates of image phase, improve signal accuracy when combining images, and improve accuracy of quantitative diffusion measurement.

The proposed AIR Recon DL feature has been developed under GE HealthCare's quality system and is at least as safe and effective as the earlier version of AIR Recon DL that is the legally marketed predicate device. For both the proposed AIR Recon DL feature and the predicate device, the primary question of safety and effectiveness is that of image quality. Performance data that were collected demonstrate the proposed AIR Recon DL feature provides an adequate level of image quality appropriate for diagnostic use. The performance testing did not identify any new hazards, adverse effects, safety concerns, or performance concerns that are significantly different from those associated with MR imaging in general. Therefore, GE HealthCare believes that proposed modified version of AIR Recon DL is substantially equivalent to the predicate device and is safe and effective for its intended use.