August 13, 2026

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

Re: K253808
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: July 14, 2026
Received: July 14, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.	K253808

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 (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	August 12, 2026
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 a purchasable software option key.

The proposed device extends the compatibility of AIR Recon DL to Zero Echo Time (ZTE) sequences and includes a new deep-learning (DL) based image algorithm designed to reduce noise, ringing, and an optional chemical shift reduction. It is embedded in the base software build of the MR system and structured as a software option and is purchasable using its own software option key (separate from the predicate device).

The training datasets were derived from a database that is proprietary to GE HealthCare. The data were subject to additional augmentations including rotations, flips, scaling, cropping, additive noise, and additive phase, which helped generate large sets of unique training and validation images.

The convolutional network receives the input image and estimates the two residuals. The network is trained by trying to match the network-estimated residuals with the actual residuals.

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 and the primary change involves the addition of a new convolutional neural network that allows the estimation and removal of noise and ringing artifacts for ZTE based MR images. Additionally, the neural network is able to reduce the severity of chemical shift artifacts seen in ZTE images. The chemical shift reduction is optional and can be enabled from the UI.

Summary of Nonclinical Testing

The new DL ZTE model has undergone non-clinical bench testing to evaluate the feature and its impact on image quality. Phantoms were used to evaluate the changes in the SNR, sharpness, and chemical shift reduction (DL CSR).

Signal-to-noise ratio was quantified using pairs of sequentially acquired images. The signal was averaged from a large region of interest (ROI) placed in a uniform region in the first image; noise was proportional to the standard deviation in the same ROI in the corresponding difference image. The AIR Recon DL reconstructed images have a higher SNR than the conventional reconstruction, and the SNR increases as the denoising setting changes from low to high. This demonstrates that *AIR Recon DL ZTE and DL CSR can increase the SNR of the images while scan time is fixed*.

Edge sharpness was evaluated by plotting line profiles across the grid in the ACR MRI phantom. Sharpness was quantified by comparing the peak slope in the line profile in the AIR Recon DL ZTE images relative to the conventionally reconstructed images. The DL ZTE reconstruction yielded a sharpness increase of 1.15 and DL CSR reconstruction yielded an improvement of sharpness of about 1.14.

For chemical shift reduction evaluation, a fat-water phantom was scanned at various bandwidth-per-pixel settings and the data was reconstructed with the conventional reconstruction as well as the DL ZTE and DL CSR versions of the model. The efficacy of chemical shift artifact reduction is assessed using the RMS error of the gradient of 1000 line profiles across the fat-water interface. With the conventional reconstruction, lower bandwidth scans show a larger RMS error correctly indicating a larger chemical shift artifact. With the addition of DL CSR, the RMS error is greatly reduced, and the RMS error for the lower bandwidth scans

is closer to that seen with the larger bandwidth, indicating that *AIR Recon DL ZTE can reduce the chemical shift artifacts seen in the ZTE images*.

Summary of Clinical Testing

An assessment was conducted with a U.S. Board Certified Radiologist to evaluate the diagnostic quality of images acquired separately from the training dataset and reconstructed with AIR Recon DL with DL ZTE. The study included 35 datasets of previously acquired de-identified cases of various anatomies including the spine (9 datasets), brain (6 datasets), lung (4 datasets), wrist (4 datasets), knee (3 datasets), skull (3 datasets) ankle (2 datasets), shoulder (2 datasets), hip (2 datasets) and finger (1 dataset). These datasets included pathological features such as compression fractures, corticomedullary differentiation of the brain, and hilar lymphadenopathy. After review and assessment, it was concluded by the radiologist that AIR Recon DL with DL ZTE produces images of diagnostic quality.

Clinical Publications

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

No.	Publication
1	M. Kaniewska, F. Zecca, C. Obermüller, F. Ensle, E. Deininger-Czermak, M. Lohezic, and R. Guggenberger, "Deep learning reconstruction of zero-echo time sequences to improve visualization of osseous structures and associated pathologies in MRI of cervical spine," Insights into Imaging, vol. 16, no. 29, 2025. doi: 10.1186/s13244-025-01902-0
2	L. Peng, X. Pan, H. Liang, T. Li, S. Zhou, W. Gao, X. Lu, and X. Rong, "Deep learning reconstruction enhances bone visualization in zero echo time MRI for cervical spondylosis: A prospective study," European Journal of Radiology, vol. 191, 112310, 2025. doi: 10.1016/j.ejrad.2025.112310
3	K. Bae, J. Lee, Y. Jung, J. de Arcos, and K. N. Jeon, "Deep learning reconstruction for zero echo time lung magnetic resonance imaging: impact on image quality and lesion detection," Clinical Radiology, 2024. doi: 10.1016/j.crad.2024.07.011
4	F. Ensle, F. Abel, M. Lohezic, C. Obermüller, and R. Guggenberger, "Deep learning reconstruction for optimized bone assessment in zero echo time MR imaging of the knee," European Journal of Radiology, vol. 179, 111663, 2024. doi: 10.1016/j.ejrad.2024.111663
5	J. Yi, S. Hahn, H.-J. Lee, S. Lee, S. Park, J. Lee, J. de Arcos, and M. Fung, "Deep learning reconstruction of zero echo time magnetic resonance imaging: diagnostic performance in axial spondyloarthritis," European Radiology, 2025. doi: 10.1007/s00330-025-11843-3
6	C. Lee, J. Lee, S. Mandava, M. Fung, Y. J. Choi, K. J. Jeon, and S.-S. Han, "Deep learning image enhancement for confident diagnosis of TMJ osteoarthritis in zero-TE MR imaging," Dentomaxillofacial Radiology, vol. 54, no. 4, pp. 302–306, 2025. doi: 10.1093/dmfr/twae063
7	L. Carretero-Gómez, M. Fung, F. Wiesinger, M. Carl, G. McKinnon, J. de Arcos, S. Mandava, S. Arauz, E. Sánchez-Lacalle, S. Nagrani, J. M. López-Alcorocho, E. Rodríguez-Íñigo, N. Malpica, and M. Padrón, "Deep learning-enhanced zero echo time MRI for glenohumeral assessment in shoulder instability: a comparative study with CT," Skeletal Radiology, 2024. doi: 10.1007/s00256-024-04830-0
8	F. Ensle, M. Kaniewska, M. Lohezic, and R. Guggenberger, "Enhanced bone assessment of the shoulder using zero-echo time MRI with deep-learning image reconstruction," Skeletal Radiology, 2024. doi: 10.1007/s00256-024-04690-8

9	C. Rhee, J.-Y. Hwang, J. W. Choi, Y. J. Cho, S. Lee, J.-E. Cheon, and Y. H. Choi, "Deep learning-enhanced zero echo time silent brain magnetic resonance imaging in infants without sedation," Pediatric Radiology, 2025. doi: 10.1007/s00247-025-06413-0
10	D Lepot, C Chabot, G Duchêne, S Mandava, M Fung, J Poujol, M C Vekemans, P Triqueneaux, N Watté, O Gheysens, N Michoux, F E Lecouvet "Zero echo time MRI with deep learning reconstruction and chemical shift correction for detecting osteolytic myeloma lesions," European Radiology Experimental, 2026. https://doi.org/10.1186/s41747-026-00734-x

No.	Abstract
1	J. de Arcos, S. Mandava, M. Lebel, F. Wiesinger, C. Cretu, P. Wielopolski, J. Hernández Tamames, and P. Ciet, "Advanced ZTE MR Lung Imaging: A Deep Learning Approach to Enhance SNR and Reduce Artifacts," abstract. https://doi.org/10.58530/2025/3855 abstract number 3855
2	M. Han, P. Wang, J. D. Baal, M. M. Fung, S. Mandava, S. Majumdar, V. Shah, and C. T. Chin, "Clinical Utility of Deep-Learning Reconstructed Zero-Echo Time MRI for Assessing Cervical Spine Degeneration in Comparison to CT," abstract. RSNA 2024
3	M. Han, P. Wang, C. Wang, J. D. Baal, S. Mandava, M. M. Fung, S. Majumdar, V. N. Shah, and C. T. Chin, "Deep Learning–Based Chemical Shift Artifact–Corrected Zero–Echo Time MRI for the Cervical Spine," abstract. *Proc Intl Soc Magn Reson Med*. 2025;33:3134. doi:10.58530/2025/3134.
4	F. M. Callaghan, M. Schmidt, S. Mandava, M. Lohezic, and C. Kellenberger, "Thoracic Bone MRI in Pediatric Patients Using Deep Learning-Enhanced ZTE," abstract, ESPR, Seville, Spain, 2024. Eastern Society of Pediatric Research (ESPR) 2024
5	N. Kocher, C. Kellenberger, M. Zellner, R. Kottke, and S. Sirin, "ZTE sequences with AI-based image reconstruction for 3D evaluation of the temporomandibular joint and craniofacial bones in children with juvenile idiopathic arthritis," abstract. Eastern Society of Pediatric Research (ESPR) 2023

Conclusion Drawn from Performance Testing

The nonclinical and clinical testing demonstrated that AIR Recon DL with ZTE satisfies the product claims that it can improve SNR and reduce chemical shift artifacts.

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 AIR Recon DL is substantially equivalent to the predicate device and is safe and effective for its intended use.