



June 5, 2025

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

Re: K243667

Trade/Device Name: Sonic DL
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: May 6, 2025
Received: May 6, 2025

Dear Emily Fang:

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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

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

Submission Number (if known)

K243667

Device Name

Sonic DL

Indications for Use (Describe)

Sonic 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. Sonic DL reconstructs MR images from highly under-sampled data, and thereby enables highly accelerated acquisitions. Sonic DL is intended for imaging patients of all ages. Sonic DL is not limited by anatomy and can be used for 2D cardiac cine imaging and 3D Cartesian imaging using fast spin echo and gradient echo sequences. Depending on the region of interest, contrast agents may be used.

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.

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K243667

510(k) Summary

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

Date	November 25, 2024
Submitter	GE Medical Systems, LLC 3200 N. Grandview Blvd. Waukesha, WI 53188
Primary Contact	Emily Fang Regulatory Affairs Leader 609-285-9878 Emily.Fang@gehealthcare.com
Secondary Contact	Glen Sabin Regulatory Affairs Director 262-894-4968 Glen.Sabin@gehealthcare.com
Device Trade Name	Sonic DL
Common/Usual Name	MR System
Classification Name	Magnetic Resonance Diagnostic Device
Regulation Number	21 CFR 892.1000
Product Code	LNH
Predicate Device(s)	Sonic DL (K223523)

Device Description

Sonic DL is a software feature intended for use with GE HealthCare MR systems. It includes a deep learning based reconstruction algorithm that enables highly accelerated acquisitions by reconstructing MR images from highly under-sampled data. Sonic DL is an optional feature that is integrated into the MR system software and activated through purchasable software option keys.

	Sonic DL Cine	Sonic DL 3D
Pulse Sequence Compatibility	FIESTA Cine	Fast Spin Echo (3D FSE) Gradient Echo (3D GRE)
Anatomic Coverage	Cardiac	All anatomies
Field Strength Compatibility	1.5T, 3.0T	1.5T, 3.0T, 7.0T
Contrast Compatibility	Yes	Yes
Maximum Acceleration	12	Up to 12

Indications for Use

Sonic 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. Sonic DL reconstructs MR images from highly under-sampled data, and thereby enables highly accelerated acquisitions. Sonic DL is intended for imaging patients of all ages. Sonic DL is not limited by anatomy and can be used for 2D cardiac cine imaging and 3D Cartesian imaging using fast spin echo and gradient echo sequences. Depending on the region of interest, contrast agents may be used.

Comparison of Technological Characteristics

The proposed Sonic 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, K223523. The predicate device used deep learning convolutional neural networks to reconstruct MR images from highly under-sampled 2D cardiac cine acquisitions (also known as “Sonic DL Cine”). The proposed Sonic DL feature has been extended to include a new deep learning convolutional neural network for use with 3D Cartesian acquisitions (“Sonic DL 3D”). The proposed Sonic DL includes both Sonic DL Cine, unchanged from the predicate device, and the new Sonic DL 3D.

Summary of Nonclinical Testing

The Sonic DL 3D model has been evaluated using data generated from digital reference objects (DROs) and MR scans of physical ACR phantoms. Comparative image quality metrics (Peak-Signal-to-Noise (PSNR), Root-Mean-Square Error (RMSE), and Structural Similarity Index Measure (SSIM)), resolution, and low contrast detectability were measured at varied acceleration factors, contrasts, and noise levels. Measurements were taken using fully sampled data as reference and compared against a conventional GE HealthCare acquisition scheme and reconstruction algorithm using ARC + HyperSense.

The nonclinical testing indicated that Sonic DL 3D at all acceleration factors (up to 12) demonstrated PSNR and SSIM equal to or above 30dB and 0.8 respectively, preserved resolution grid structure and resolution. Medium or high contrast detectability was retained at all accelerations, and low contrast detectability was retained at lower acceleration factors but decreased as acceleration factor increased. In comparison to conventional reconstruction methods, Sonic DL 3D exhibited comparable or better performance in preserving small structures and low contrast detectability.

A task-based study using a convolutional neural network ideal observer (CNN-IO) was conducted to further quantify the low contrast detectability of Sonic DL 3D. Compared to parallel imaging and zero-filled reconstructions, Sonic DL 3D had superior performance in every test condition. Detectability with Sonic DL 3D decreased as the acceleration rate increased, but at a more gradual rate than parallel imaging or zero-filling. Low contrast detectability with Sonic DL at the recommended acceleration rates (tabulated below) was non-inferior to more modestly accelerated conventional reconstruction methods. AUC analysis indicates that Sonic DL 3D at 8x has comparable low contrast detectability to parallel imaging at 4x, and Sonic DL 3D at 12x is comparable in detectability to parallel imaging at 8x. While average low contrast detectability is reduced at higher acceleration rates, the use of rates above those recommended may be acceptable in certain clinical scenarios.

The stability of the Sonic DL 3D model was shown by reconstructing *in vivo* datasets including different anatomies, contrasts, and field strengths, with previously unseen data inserted into the image. Images were reconstructed at different acceleration factors with varied intensities and locations of the inserted

data. Results showed that dataset integrity was preserved across all cases, and the model exhibited a low risk of hallucination.

Overall, Sonic DL 3D was shown to accelerate 3D MR acquisitions up to 12-fold while outperforming conventional parallel imaging and compressed sensing at similar acceleration. The nonclinical testing did not identify any adverse impacts to image quality or other concerns related to safety and performance at the recommended acceleration rates; extreme acceleration rates were found to have decreased low contrast detectability.

Summary of Clinical Testing

Quantitative Post Processing

Images were evaluated to confirm that the use of Sonic DL 3D does not adversely impact downstream quantification. Volumetric measurements of key brain tissues were performed to assess whether Sonic DL 3D images have similar quantitative analysis results compared to ARC + HyperSense images. Sonic DL 3D and ARC + HyperSense images were retrospectively generated from 15 fully-sampled data sets acquired at GE HealthCare in Waukesha, USA from 1.5T, 3.0T, and 7.0T scanners. Data was also generated with and without AIR Recon DL to evaluate the compatibility of Sonic DL 3D and AIR Recon DL in the reconstruction pipeline.

Across all sampling methods and quantitative measurements, it was found that the 95% confidence interval for relative mean absolute error (MAE) was less than 5% for most regions and 3% for the Hippocampal Occupancy Score (HOS). The 95% confidence interval for the intra-class correlation coefficient exceeded 0.75 across all comparisons, aligning with acceptance criteria established in published literature. This analysis highlights the robustness of Sonic DL 3D, and that Sonic DL 3D and AIR Recon DL are mutually compatible at various acceleration factors.

Bland-Altman analysis confirmed that Sonic DL would not adversely impact quantification compared to either the fully sampled acquisitions or the clinical standard ARC + HyperSense reconstructions. The observed biases were small relative to the magnitude of the measured metrics, indicating minimal differences between methods.

Whole Brain Volume (mL)		
	Mean Diff	95% CI
Fully sampled vs ARC 2x1x1.2	1.1	[-4.4, 6.5]
Fully sampled vs Sonic DL 4	1.4	[-2.4, 5.3]
Fully sampled vs Sonic DL 12	6.8	[-4.9, 18.6]

Cortical Gray Matter Volume (mL)		
	Mean Diff	95% CI
Fully sampled vs ARC 2x1x1.2	3.0	[1.2, 4.9]
Fully sampled vs Sonic DL 4	3.2	[0.7, 5.6]
Fully sampled vs Sonic DL 12	9.1	[2.1, 16.0]

HOC Average Occupancy		
	Mean Diff	95% CI
Fully sampled vs ARC 2x1x1.2	0.004	[-0.007, 0.014]
Fully sampled vs Sonic DL 4	0.007	[-0.009, 0.023]
Fully sampled vs Sonic DL 12	0.014	[-0.018, 0.046]

Cerebral White Matter Volume (mL)		
	Mean Diff	95% CI
Fully sampled vs ARC 2x1x1.2	-1.5	[-4.4, 1.5]
Fully sampled vs Sonic DL 4	-2.0	[-5.2, 1.3]
Fully sampled vs Sonic DL 12	-2.3	[-10.1, 5.5]

Ventricle Total Volume (mL)		
	Mean Diff	95% CI
Fully sampled vs ARC 2x1x1.2	-0.1	[-0.3, 0.2]
Fully sampled vs Sonic DL 4	-0.1	[-0.4, 0.1]
Fully sampled vs Sonic DL 12	-0.2	[-0.8, 0.4]

Clinical Evaluation Studies

Additionally, two Likert-score based clinical studies were performed using Sonic DL 3D images acquired from clinical sites and from healthy volunteers scanned at GE HealthCare facilities. In one study, three radiologists were asked to evaluate the diagnostic quality of images acquired and reconstructed with Sonic DL 3D and with a comparator, ARC + HyperSense, for 120 de-identified cases of brain, spine, and extremities as summarized below:

Number of image series evaluated:	120
Number of unique subjects:	54
Patients:	48
Healthy Volunteers:	6
Sites contributing data:	7
United States:	4
Outside of United States:	3
Gender of subjects	
Male:	26
Female:	28
Age range of subjects:	11-80 years
Pathology:	Subjects from clinical sites included examples of various pathologies representing a mixture of small, large, focal, diffuse, hyper- and hypo-intense lesions
Contrast:	Contrast agents were used in a subset of the data, as clinically indicated
Equipment Used:	GE HealthCare 1.5T, 3.0T, and 7.0T MR Systems

The results showed that Sonic DL 3D images are of diagnostic quality while yielding a substantial reduction in the scan time compared to ARC + HyperSense images.

Radiologists were also asked to comment on the presence of any pathology in the images. Analysis of these comments showed that images acquired and reconstructed with Sonic DL 3D agreed with those obtained with ARC + HyperSense across various anatomical subgroups and field strengths. These results demonstrate that pathology seen in the ARC + HyperSense images can be accurately retained in Sonic DL 3D images.

In a second study, three radiologists evaluated clinically relevant anatomic structures in Sonic DL 3D brain images. The study included 120 additional cases retrospectively generated from 30 fully-sampled acquisitions obtained at 1.5T, 3.0T, and 7.0T field strengths. Each case was generated from fully sampled data that was either (1) under-sampled to simulate Sonic DL 3D accelerations of 4 to 10 then reconstructed with Sonic DL 3D or (2) under-sampled to simulate an ARC acceleration factor of 2x1 and a HyperSense factor of 1.2. All cases were collected internally at GE HealthCare.

Despite the higher acceleration factors used, the Sonic DL 3D images received diagnostic scores in all anatomic structures and at all acceleration factors investigated. The scores gradually declined with increasing acceleration factors yet retained diagnostic quality overall. The results of this study confirm that Sonic DL 3D provides diagnostic quality images at the range of acceleration factors studied.

Assessment of Representative Data

In addition to the clinical evaluations described above, supplementary testing was done to further support broad use of Sonic DL 3D. Representative datasets with different anatomies, contrast weightings, with/without contrast agent, orientations, with/without AIR Recon DL, and acceleration factors up to 12 were assessed for Sonic DL 3D and compared to standard clinically appropriate protocols using ARC + HyperSense. Breast and liver data were collected from academic/clinical partners while the remaining images were acquired on a volunteer cohort internal to GE HealthCare.

Assessment of the representative data confirmed that Sonic DL 3D performs well across varied imaging conditions, retaining relevant anatomical details without structural losses or concerning artifacts.

Clinical Publications

The following peer-reviewed studies provide further quantitative and qualitative evidence of the ability of Sonic DL to improve acquisition speed and/or resolution across various clinical applications in the brain, joints, breast, prostate, and abdomen:

- [1] Shintaku T, Ide S, Nagaya H, Ishimoto Y, Watanabe K, Oyu K, et al. Improved assessment of juxtacortical lesions in multiple sclerosis using highly-accelerated high-resolution double inversion recovery MR imaging with deep learning-based reconstruction. *Magn Reson Med Sci*. 2025.
- [2] Ishimoto Y, Shintaku T, Ide S, Watanabe K, Oyu K, Kasai S, et al. Improved assessment of microbleeds by highly-accelerated 3D SWAN imaging with deep learning-based reconstruction. *ISMRM* 2025.
- [3] Carretero L, Nunes B, Zhu X, Sanchez-Lacalle E, Sundaran D, Dholakia J, et al. 2-Minute 3D FSE Knee MRI with 10-fold accelerated Sonic DL – Rapid morphometric and qualitative assessment of Cartilage and Meniscus. *ISMRM* 2025.
- [4] Milshteyn E, Pohl M, Cochran RL, Gaddipati A, Venkatachari A, Kolupar T, et al. Evaluation of Accelerated 2D and 3D Acquisition Strategies for T2-Weighted MRI of the Prostate. *ISMRM* 2025.
- [5] Watanabe K, Kasai S, Umemura Y, Tatsuo S, Oyu K, Nozaki A, et al. 0.9mm isotropic 1min MPRAGE using highly-accelerated Deep learning Reconstruction for Brain Structural Analysis. *ISMRM* 2024.
- [6] Sato K, Tanaka S, Murayama R, Takayama Y, Nozaki A, Zhu X, et al. Fast hepatobiliary phase gadoxetate-enhanced imaging under breath-holding utilizing DL reconstruction (Sonic DL): preliminary experience. *ISMRM* 2025.
- [7] Wang P, Lu C, Keen K, Wilmes LJ, Chou SH, Chung M, et al. Shortening 3D T2-Weighted Breast MRI scan time using deep learning based reconstruction: A phantom and patient reader study. *ISMRM* 2025.
- [8] Sato K, Tanaka S, Murayama R, Takayama Y, Nozaki A, Zhu X, et al. Quadruple arterial phase dynamic EOB imaging using a novel DL reconstruction visualizing aortic wax and wane phenomenon: preliminary results. *ISMRM* 2025.

Recommended Acceleration Ranges

The following table summarizes the maximum acceleration factors tested and the recommended acceleration ranges for each anatomical region. These values were established through comprehensive performance evaluations including model observer testing, quantitative volumetric analysis, and clinical image quality assessments.

Anatomy	Maximum Acceleration Tested	Recommended Default Acceleration Range		
		1.5T	3.0T	7.0T
Brain	12	4 – 6	6 – 8	8 – 10
Spine	12	4 – 6	6 – 8	-
Musculoskeletal	12	4 – 6	8 – 10	8 – 10
Abdomen	12	4 – 6	8 – 10	-
Pelvis	12	4 – 6	6 – 8	-
Breast	10	4 – 6	6 – 8	-

Conclusion Drawn from Performance Testing

The nonclinical and clinical testing demonstrated that Sonic DL 3D satisfies the product claims of reducing scan time while preserving diagnostic image quality, providing acceleration factors up to 12, and can enable the acquisition of higher resolution images with similar scan times.

Note that at very high acceleration factors, there may be a slight degradation in image quality affecting detectability for small low contrast lesions. Clinicians should use their best judgement in making these tradeoffs based on the specifics of the patient and clinical scenario, as is customary in clinical standard of care.

The proposed Sonic DL feature has been developed under GE HealthCare's quality management system and is at least as safe and effective as the earlier version of Sonic DL that is the legally marketed predicate device. For both the proposed Sonic 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 Sonic 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 Sonic DL is substantially equivalent to the predicate device and is safe and effective for its intended use.