



February 6, 2026

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

Re: K253780
Trade/Device Name: SIGNA™ Bolt
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: November 26, 2025
Received: November 26, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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

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

510(k) Number (if known)

K253780

Device Name

SIGNA™ Bolt

Indications for Use (Describe)

The SIGNA™ Bolt system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by the SIGNA™ Bolt system reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

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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K253780

510(k) Summary

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

Date	November 26, 2025
Submitter	GE Medical Systems, LLC 3200 N. Grandview Blvd. Waukesha, WI 53188
Primary Contact	Emily Fang Regulatory Affairs Leader 609-285-9878 signa.bolt.premarket@gehealthcare.com
Secondary Contact	Sandra Bahling Senior Regulatory Affairs Leader 262-720-8872 Sandra.Westphal@gehealthcare.com Glen Sabin Regulatory Affairs Director 262-894-4968 Glen.Sabin@gehealthcare.com
Device Trade Name	SIGNA™ Bolt
Common/Usual Name	MR System
Classification Name	Magnetic Resonance Diagnostic Device
Regulation Number	21 CFR 892.1000
Product Code	LNH, LNI, MOS
Predicate Device(s)	SIGNA™ Premier (K193282)
Reference Device(s)	SIGNA™ Victor (K223439)

Device Description

SIGNA™ Bolt is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times, and is designed for improved patient comfort and workflow. The system features a 3.0T superconducting magnet with a 70 cm bore size and can image in the sagittal, coronal, axial, oblique, and double oblique planes, using various pulse sequences, imaging techniques and reconstruction algorithms. SIGNA™ Bolt is designed to conform to NEMA DICOM standards.

The SIGNA™ Bolt system will be offered as two commercial configurations with the following features:

Specification	SIGNA™ Bolt – SuperXG Gradient	SIGNA™ Bolt – SuperXF Gradient
Magnet	3.0T superconducting magnet with a wide (70 cm) bore size and active shielding	
Maximum Gradient Strength	80 mT/m	65 mT/m
Maximum Slew Rate	200 T/m/s	200 T/m/s

Specification	SIGNA™ Bolt – SuperXG Gradient	SIGNA™ Bolt – SuperXF Gradient
RF Transmit	A liquid cooled In-Scan-Room RF transmit architecture with a peak power capability of 36 kW and 3.0T Platform Body Coil	
RF Receive Chain	162 Ch available	130 Ch available
Patient Table	Detachable SIGNA One Patient Table with embedded 3.0T AIR PA XL coil and up to four 32-channel high density auto-coil sensing connection ports	
Power Rating	113 kVA	90 kVA
Software	Software platform featuring various productivity enhancement features, designed to improve workflow and reduce scan time - AIRx (previously cleared in K183231) – AI-based automated slice prescription tool now extended with new deep learning models for spine and prostate imaging - SIGNA One Camera – Real-time AI-enabled image guidance that assists with automated patient positioning	
Gating Options	Wired, wireless, and contactless physiological gating options	

Comparison of Indications for Use

The indications for use have not been changed compared to the predicate, other than to reflect the SIGNA™ Bolt product name:

The SIGNA™ Bolt system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by the SIGNA™ Bolt system reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Therefore, the intended use is the same as the predicate device in accordance with the FDA guidance “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”, issued on July 28, 2014.

Comparison of Technological Characteristics

Overall, SIGNA™ Bolt employs the same fundamental scientific technology and operating principles as the predicate device and reference device.

There are some differences in characteristics between the proposed device and the predicate/reference devices, as summarized below:

Subsystem or Component	Predicate Device SIGNA™ Premier (K193282)	Proposed Device SIGNA™ Bolt	Comments
Magnet	3.0T superconducting magnet with active shielding.		Identical. SIGNA™ Bolt uses the same type of magnet as used in the predicate device.
Gradient Coil	HRMW gradient coil with water-cooled, active-shielded design.	ZRMW gradient coil with water-cooled, active-shielded design.	Substantially Equivalent. The ZRMW gradient coil decreases heat generation and lowers the temperature of the inner bore. These differences do not impact safety or efficacy.
RF Transmit Subsystem	A liquid cooled RF transmit architecture with a peak power capability of 30 kW and 3.0T RF body coil.	A liquid cooled In-Scan-Room RF transmit architecture with a peak power capability of 36 kW and 3.0T Platform Body Coil.	Substantially Equivalent. The Platform Body Coil used in SIGNA™ Bolt is the same as the predicate device with design modifications to reduce heat dissipation. SIGNA™ Bolt also uses a newly designed In-Scan-Room (ISR) Transmit Driver which moves all the transmit driver components except the ISR Support Unit inside the scan room as compared to the equipment room for the predicate device. These modifications do not raise any new concern of safety or effectiveness.
RF Receive Subsystem	3.0T Digitize-Per-Pin (DPP) receive chain architecture.		Identical. SIGNA™ Bolt uses the same type of RF receive subsystem as used in the predicate device.
Gating Options	Respiratory peripheral and cardiac gating with wired and wireless connection.	Respiratory peripheral and cardiac gating with wired and wireless connection. Contactless peripheral cardiac and respiratory gating.	Substantially Equivalent. SIGNA™ Bolt offers the same wired and wireless gating capabilities as the predicate device. SIGNA™ Bolt introduces contactless gating, enabling peripheral cardiac and respiratory triggered MR exams without the need for physical attachment of monitoring accessories. This modification does not raise any new concern of safety or effectiveness.
Software Features	Comprehensive suite of software features, pulse sequences, and image processing applications to support MR imaging of all anatomies.		Substantially Equivalent. SIGNA™ Bolt software is based off that of reference device SIGNA™ Victor, bringing additional parity with features available on the predicate device software platform along with modifications and enhancements to existing features. The modifications do not raise any new concern of safety or effectiveness.

Summary of Nonclinical Testing

The SIGNA™ Bolt system was developed and tested under the same design controls, risk management processes, and GE HealthCare quality system as the predicate device SIGNA™ Premier (K193282) to demonstrate substantial equivalence in safety and performance.

The following quality assurance measures were implemented during the development of SIGNA™ Bolt, consistent with those applied to the predicate device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Unit-Level Testing (Verification)
- System Integration Testing (Verification)
- Performance Testing (Verification)
- Simulated Use Testing (Validation)

Testing was conducted in accordance with the following voluntary consensus standards:

- ANSI/AAMI/IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-33
- IEC TS 60601-4-2
- IEC 62304
- ISO 10993-1
- IEC 62464-1
- NEMA MS 1
- NEMA MS 3
- NEMA MS 4
- NEMA MS 6
- NEMA MS 8
- NEMA MS 9
- NEMA MS 14
- NEMA PS 3.1 - 3.20

Software verification and validation testing was conducted and documented in accordance with the FDA guidance “Content of Premarket Submissions for Device Software Functions” issued on June 14, 2023.

Cybersecurity testing was completed and documented in accordance with the FDA guidance “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” issued on June 27, 2025.

Contactless Gating

Verification and validation testing confirmed that the contactless gating feature meets its performance specifications by accurately detecting and displaying respiratory and peripheral cardiac waveforms without the need for physical accessories. Contactless gating also supports use of these waveforms for triggering MR acquisitions across multiple anatomical regions.

SIGNA One Camera

The SIGNA One Camera is intended solely for use during the exam setup process prior to the initiation of the localizer scan and does not perform diagnostic imaging or evaluation. Accordingly, performance testing focused on assessing the deep learning model landmark inference accuracy using diverse datasets collected from 80 volunteers in the US and China. To ensure unbiased evaluation, the test dataset was entirely separate from the training and validation datasets. Accuracy was evaluated by comparing the MR system coordinates of the camera-predicted anatomical landmarks against ground truth annotations. The SIGNA One Camera met the predefined acceptance criterion of 90%, achieving successful detection in up to 99% of cases across all evaluated anatomical regions.

A time on task study was also conducted with 11 MR Scan Operators as participants to assess the efficiency and reliability of the SIGNA One Camera landmarking workflow compared to conventional laser landmarking. Results demonstrated that the camera workflow consistently enabled faster setup times for landmarking. Additionally, the camera achieved a 97% success rate in landmark acceptance with the addition of anatomical obstructions, exceeding the predefined acceptance criterion of 95%.

AIRx

The AIRx feature is intended to automatically determine scan planes aligned to specific anatomical structures before the initiation of a scan. It was initially cleared for brain imaging under K183231 and subsequently extended to include knee imaging. In this submission, AIRx functionality has been further expanded to support imaging of the spine and prostate.

Performance testing was conducted on the AIRx Spine deep learning models using a dedicated dataset derived from 376 subjects. Data were sourced from multiple clinical sites and internal GE HealthCare sites to ensure diversity in anatomy, field strength, imaging protocols, pathology, and presence of implants. The test dataset was held separate from training and validation data. All models met their predefined acceptance criteria.

Comparative studies demonstrated that AIRx Spine reduced scan prescription times compared to manual workflows and minimized inter-operator variability, as confirmed by Structural Similarity Index (SSIM) analysis and visual comparisons. AIRx Spine successfully adapted prescriptions to patient-specific spinal curvatures, enabling accurate multi-slice, multi-angle prescriptions for cervical, thoracic, and lumbar stations. Additionally, AIRx Spine successfully automated the setup of Pars Interarticularis and Cervical Foramina scans, reducing the variability in manual prescription due to the complex angle and small size of these structures. All tests met predefined acceptance criteria with no deviations or failures, supporting the performance claims for AIRx Spine.

Performance testing was conducted on the six deep learning models that comprise the AIRx Prostate feature, evaluating automated prostate scan plane prescription using SSFSE localizer images across diverse datasets from clinical sites in the US and Europe. A total of 785 exams were used for the test dataset, which was kept separate from the training and validation data. All models met predefined acceptance criteria, confirming robustness to variations in anatomy, pathology, and presence of implants.

GE HealthCare intends to obtain clearance for AIRx Spine and AIRx Prostate on GE HealthCare's 3.0T and 1.5T MR Systems.

Summary of Clinical Testing

SIGNA™ Bolt did not require clinical studies to support substantial equivalence. Sample clinical images have been included in this submission in accordance with the FDA Guidance “Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices” issued on October 10, 2023.

A U.S. Board Certified radiologist reviewed these images and attested that images produced by SIGNA™ Bolt are of sufficient quality for diagnostic use.

Conclusions Drawn from Performance Testing

In conclusion, GE HealthCare considers the SIGNA™ Bolt to be as safe, as effective, with performance that is substantially equivalent to the predicate device.