September 11, 2025

GE Medical Systems, LLC
Xinyu Song
Lead Specialist, Regulatory Affairs - MR
3200 N Grandview Blvd.
Waukesha, Wisconsin 53188

Re: K251399
Trade/Device Name: SIGNA™ Sprint
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: August 13, 2025
Received: August 13, 2025

Dear Xinyu Song:

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,

NINGZHI LI -S Digitally signed by NINGZHI LI -S

for
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.	K251399

Please provide the device trade name(s).

SIGNA™ Sprint

Please provide your Indications for Use below.

The SIGNA™ Sprint 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 SIGNA™ Sprint 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.

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)

K251399

510(k) Summary

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

Date	September 10, 2025
Submitter	GE Medical Systems, LLC 3200 N. Grandview Blvd. Waukesha, WI USA 53188
Primary Contact Person	Xinyu Song Lead Specialist, Regulatory Affairs, MR GE HealthCare Phone: 86 186 1188 4503 E-mail: Xinyu.Song@gehealthcare.com
Secondary Contact Person	Glen Sabin Director - Regulatory Affairs, MR Strategy GE HealthCare Phone: 262 894-4968 E-mail: Glen.Sabin@gehealthcare.com
DeviceTrade Name	SIGNA™ Sprint
Common/Usual Name	Magnetic Resonance Diagnostic Device
Classification Names	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000
Product Code	LNH, LNI, MOS
Predicate Device	SIGNA™ Premier (K193282)
Reference Device	(1) SIGNA™ Artist (K202238) (2) SIGNA™ Champion (K233728)

Reason for Submission:

This 510(k) is being submitted due to the introduction of SIGNA™ Sprint, a new 1.5T MR system from GE HealthCare.

Device Description:

SIGNA™ Sprint is a whole-body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan time. The system uses a combination of time-varying magnet fields (Gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. The system can image in the sagittal, coronal, axial, oblique, and double oblique planes, using various pulse sequences, imaging techniques and reconstruction algorithms. The system features a 1.5T superconducting magnet with 70cm bore size. The system is designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).

Key aspects of the system design:

- Uses the same magnet as a conventional whole-body 1.5T system, with integral active shielding and a zero boil-off cryostat.
- A gradient coil that achieves up to 65 mT/m peak gradient amplitude and 200 T/m/s peak slew rate.
- An embedded body coil that reduces thermal and enhance intra-bore visibility.
- A newly designed 1.5T AIR Posterior Array.
- A detachable patient table.
- A platform software with various PSD and applications, including the following AI features:
    - AIRx™ (Cleared in K183231)
    - AIR™ Recon DL (Cleared in K202238)
    - Sonic DL™ (Cleared in K223523)

Indications for Use

The SIGNA™ Sprint 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 SIGNA™ Sprint 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.

Comparison of Indications for Use

The changes in technology do not impact the indications for use. The indications for use have not been changed, other than to reflect the SIGNA™ Sprint product name. Therefore, the intended use is the same 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.

Technology

The SIGNA™ Sprint employs the same fundamental scientific technology as its predicate device.

SIGNA™ Sprint is built with a superconducting magnet, gradient, RF transmit architecture, RF receive chain and software application suite.

Comparison of Technological Characteristics

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

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™ Sprint	Comments
Magnet	3.0T Superconducting Magnet with active shielding.	1.5T Superconducting Magnet with active shielding.	The magnet has same technology with different magnet field strength, and minor modification on enclosure. It is identical with Reference Device SIGNA™ Artist.
Gradient Subsystem	A gradient coil with water-cooled, active-shielded design.		The gradient coil is modified to reduced DC resistance and AC impedance for less cooling requirements.
RF Transmit Subsystem	3.0T Transmit with embedded body coil and local T/R coil.	1.5T Transmit with embedded body coil and local T/R coil.	The platform body coil is modified to reduce thermal and enhance intra-bore visibility. The RF Transmit Subsystem except body coil is identical with Reference Device SIGNA™ Artist.
RF Receive Subsystem	3.0T Digitize-Per-Pin (DPP) receive chain architecture.	1.5T Digitize-Per-Pin (DPP) receive chain architecture.	The RF Receive Subsystem uses the same technology with different RF frequency. It is identical with Reference Device SIGNA™ Artist.

Subsystem or Component	Predicate Device SIGNA™ Premier (K193282)	Proposed Device SIGNA™ Sprint	Comments
RF Coils – detachable	Comprehensive suite of 3.0T detachable coils for imaging all anatomies.	Comprehensive suite of 1.5T detachable coils for imaging all anatomies.	The RF coils use same technology with different RF frequency. They are substantial equivalent with Reference Device SIGNA™ Artist's RF coils.
RF Coil – embedded	AIR Posterior Array	1.5T AIR Posterior Array	The 1.5T AIR Posterior Array coil has the same fundamental scientific principles and similar SNR and Uniformity measurements within their operated field strength. It is substantially equivalent with SIGNA™ Premier's AIR PA coil.
Software Features	Comprehensive suite of software features, pulse sequences, and image processing applications to support MR imaging of all anatomies.		SIGNA™ Sprint uses equivalent software with predicate and reference devices.
Gating Accessories	Respiratory peripheral and cardiac gating with wireless connection.		SIGNA™ Sprint uses the identical gating accessories with predicate and reference devices.

These differences do not raise any different questions regarding 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 SIGNA™ Sprint compared to the predicate device.

Comparison of Operating Principles: The SIGNA™ Sprint functions using the same operating principles as the predicate device.

Comparison of Materials: The SIGNA™ Sprint and the predicate device both use flame retardant materials.

Comparison of Safety and Performance Testing: Both the SIGNA™ Sprint and the predicate device comply with the same safety and performance testing (see Determination of Substantial Equivalence, below).

These technological differences do not raise any different questions regarding 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 SIGNA™ Sprint compared to the predicate device.

Determination of Substantial Equivalence

Summary of Non-Clinical Tests:

The SIGNA™ Sprint and the predicate device were subject to similar risk management testing to demonstrate substantial equivalence of safety and performance.

Testing to the following voluntary standards included:

- ANSI AAMI ES60601-1
- IEC 60601-1-2
- IEC 60601-2-33
- IEC 62304
- IEC 60601-1-6
- IEC 62366-1
- ISO 10993-1
- NEMA MS 1
- NEMA MS 2
- NEMA MS 3
- NEMA MS 4
- NEMA MS 5
- NEMA MS 8
- NEMA MS 9
- NEMA MS 14
- NEMA PS 3.1 – 3.20

Both the SIGNA™ Sprint and the predicate device have a successful biocompatibility track record, as demonstrated by ISO 10993 testing and by their history of use in previously cleared devices.

The following quality assurance measures were applied to the development of the subject device, as they were for the predicate device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, the SIGNA™ Sprint, did not require clinical studies to support substantial equivalence. Sample clinical images have been included in this submission.

The sample clinical images demonstrate acceptable diagnostic image performance of the SIGNA™ Sprint in accordance with the FDA Guidance "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" issued on October 10, 2023. The image quality of the SIGNA™ Sprint is substantially equivalent to that of the predicate device.

Substantial Equivalence Conclusion:

The indications for use of the proposed device are comparable to the claimed predicate device. The SIGNA™ Sprint employs equivalent technology to the claimed predicate device. Additionally, the results from the above non-clinical tests demonstrate that the device performs as intended. Therefore, the SIGNA™ Sprint is substantially equivalent to the predicate device to which it has been compared.

Conclusion

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