October 17, 2024

GE Medical Systems, LLC
Brian Zielski
Sr. Lead Specialist, Regulatory Affairs - MR
3200 N Grandview Blvd
Waukesha, Wisconsin 53188

Re: K241242
Trade/Device Name: SIGNA MAGNUS
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI
Dated: September 10, 2024
Received: September 10, 2024

Dear Brian Zielski:

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,

Justina Tam -S

Digitally signed by Justina Tam -S
Date: 2024.10.17 14:38:06 -04'00'

for
Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241242

Device Name
SIGNA MAGNUS

Indications for Use *(Describe)*
SIGNA MAGNUS system is a head-only magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, diffusion-weighted imaging, and short scan times. SIGNA MAGNUS 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 head, neck, TMJ, and limited cervical spine on patients 6 years of age and older. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by SIGNA MAGNUS 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.

K241242

510(k) Summary

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

Date:	May 1, 2024
Submitter:	GE Medical Systems, LLC 3200 N. Grandview Blvd. Waukesha, WI 53188
Primary Contact:	Brian R. Zielski Sr. Lead Specialist, Regulatory Affairs - MR Phone: 262-227-3596 Email: brian.zielski@gehealthcare.com
Secondary Contact:	Andrew Menden Director, Regulatory Affairs - MR Phone: 262-308-5719 Email: andrew.menden@gehealthcare.com
Device Trade Name:	SIGNA MAGNUS
Common / Usual Name:	Magnetic Resonance Diagnostic Device
Classification Name:	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000
Product Code:	LNH, LNI
Predicate Device(s):	SIGNA Premier (K193282)
Reference Device(s):	SIGNA Champion (K233728)
Device Description:	SIGNA MAGNUS is a 3.0T high-performance magnetic resonance imaging system designed to support imaging of the head, neck, TMJ and limited cervical spine. The system supports scanning in axial, coronal, sagittal, oblique, and double oblique planes using a variety of pulse sequences, imaging techniques, acceleration methods, and reconstruction algorithms. The system can be delivered as a new system installation, or as an upgrade to existing compatible whole-body 3.0T MR systems from GE HealthCare.

	Key aspects of the system design: • An asymmetrically designed, head-only gradient coil that achieves up to 300 mT/m peak gradient amplitude and 750 T/m/s peak slew rate. • A graduated patient bore size, starting at 74 cm at the entry down to 37 cm at isocenter. • Uses the same magnet as a conventional whole-body 3.0T system, with integral active shielding and a zero boil-off cryostat. • Can be installed as a new system or upgraded from an existing compatible whole-body 3.0T MR system. • A dockable mobile patient table. • Oscillating Diffusion ENcoding (ODEN) - a spectral diffusion technique that uses a sinusoidal diffusion gradient waveform.
Indications for Use:	SIGNA MAGNUS system is a head-only magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, diffusion-weighted imaging, and short scan times. SIGNA MAGNUS 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 head, neck, TMJ, and limited cervical spine on patients 6 years of age and older. Depending on the region of interest being imaged, contrast agents may be used. The images produced by SIGNA MAGNUS 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.
Technology:	SIGNA MAGNUS employs the same functional scientific technology as its predicate device.
Comparison of Indications for Use:	SIGNA MAGNUS and the predicate device's Indications for Use are substantially equivalent. While the predicate is intended for all anatomies, SIGNA MAGNUS is intended for only the head, neck, TMJ, and cervical spine.

	As such, GE HealthCare considers that SIGNA MAGNUS has the same intended use 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.
Comparison of Technological Characteristics:	Overall, SIGNA MAGNUS employs the same fundamental scientific technology as the predicate device. **System Design**: Both SIGNA MAGNUS and the predicate device include the 3.0 T magnet, RF transmit architecture, RF receive chain and software application suite. However, the most notable technological difference between the SIGNA™ MAGNUS and the predicate device are: • Gradient System: The SIGNA MAGNUS can deliver a peak gradient amplitude of 300 mT/m and peak gradient slew rate of 750 T/m/s compared to the predicate's peak gradient amplitude of 80 mT/m and peak gradient slew rate of 200 T/m/s. PNS and CS thresholds are also significantly different between the two systems, allowing more performance to be used on the SIGNA MAGNUS system. • Applications: The SIGNA MAGNUS uses the SIGNA Works suite of applications with the addition of Oscillating Diffusion ENcoding (ODEN) - a spectral diffusion technique that uses a sinusoidal diffusion gradient waveform. ODEN is not offered on the predicate device. • Field-of-View (FOV): The SIGNA MAGNUS FOV (26cm x 26 cm x 26cm) is intended for head, neck, TMJ, and limited cervical spine scanning. As such, a smaller maximum imaging FOV is specified compared to the predicate device with an FOV of 50cm x 50cm x 50cm. • Bore Size: Unlike the straight cylindrical patient bore of the predicate device, the SIGNA MAGNUS

	system has a stepped progressively narrowing patient bore. The widest part at the patient bore entry accommodates the arms and torso. It has a 74 cm inner diameter. The patient bore diameter at the shoulders is narrowed to 54 cm. At the head, the SIGNA MAGNUS patient bore diameter is 37 cm compared to 70 cm for the predicate device. • Receive Channels: The SIGNA MAGNUS has 64 independent RF channels to account for the imaged anatomies of head, neck, TMJ, and limited cervical spine, compared to 146 for the predicate device which is used for whole-body imaging. • Max RF Power Output: The SIGNA MAGNUS has 7.5 kW peak total maximum RF power output compared to 30 kW for the predicate device. **Operating Principles**: SIGNA MAGNUS functions using the same operating principles as the predicate device. **Materials**: SIGNA MAGNUS and the predicate device both use the same materials. **Safety and Performance Testing**: Both SIGNA MAGNUS 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 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 MAGNUS compared to the predicate device.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: SIGNA MAGNUS 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 • IEC62464-1 • ISO 10993-1 In addition, SIGNA MAGNUS complies with applicable NEMA MS standards for MRI and NEMA PS3 standard for DICOM, as does the predicate device. Both SIGNA MAGNUS and the predicate device have demonstrated successful biocompatibility, 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 • Verification • Validation Verification documents, validation documents, and test reports have been provided for more details. No new questions of safety and effectiveness were raised during nonclinical testing. <u>Summary of Clinical Tests</u>: The subject of this premarket submission, SIGNA MAGNUS 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 SIGNA MAGNUS in accordance with the FDA Guidance “Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices” issued on

	October 10, 2023. The image quality of SIGNA MAGNUS is substantially equivalent to that of the predicate device. <u>Substantial Equivalence Conclusion</u>: The indications for use of the proposed device are comparable to the claimed predicate device. SIGNA MAGNUS 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, SIGNA MAGNUS is substantially equivalent to the predicate device to which it has been compared.
<u>Conclusion:</u>	In conclusion, GE Healthcare considers SIGNA MAGNUS to be at least as safe and effective, and its performance is substantially equivalent to the predicate device.