January 19, 2024

GE Healthcare (Tianjin) Company Limited
℅ Glen Sabin
Director - Regulatory Affairs, MR Strategy
GE Medical Systems, LLC
3200 N Grandview Blvd.
Waukesha, Wisconsin 53188

Re: K233728
Trade/Device Name: SIGNA™ Champion
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI
Dated: November 21, 2023
Received: November 21, 2023

Dear Glen Sabin:

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K233728

Device Name

SIGNA™ Champion

Indications for Use *(Describe)*

The SIGNA™ Champion 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™ Champion 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date	January 19, 2024
Submitter	GE Healthcare (Tianjin) Company Limited No. 266 Jingsan Road, Tianjin Airport Economic Area Tianjin, P.R. China 300308
Primary Contact Person	Xinyu Song Lead Specialist, Regulatory Affairs, MR GE HealthCare Phone: +86 186 1188 4503 E-mail: Xinyu.Song@ge.com
Secondary Contact Person	Glen Sabin Director - Regulatory Affairs, MR Strategy GE HealthCare Phone: 262 894-4968 E-mail: glen.sabin@ge.com
DeviceTrade Name	SIGNA™ Champion
Common/Usual Name	Magnetic Resonance Diagnostic Device
Classification Names	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000
Product Code	LNH, LNI
Predicate Device	SIGNA™ Voyager (K192426)
Reference Device	(1) SIGNA™ Victor (K223439) (2) SIGNA™ Hero (K213668)

Reason for Submission:

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

Device Description:

SIGNA™ Champion 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).

A high-level summary of significant hardware and software modifications is provided below:

Hardware changes (compared with Predicate Device SIGNA™ Voyager):

- Magnet Enclosure
- Patient Table and related support components
- Host Computer
- RF Transmit Chain
- Wireless Gating

Software Changes (compared with Reference Device 2 SIGNA™ Hero)

- Sonic DL
- AIR Recon DL

Indications for Use

The SIGNA™ Champion 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™ Champion 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

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

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

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™ Champion 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.

Comparison of Technological Characteristics

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

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

Subsystem or Component	**Predicate Device SIGNA™ Voyager (K192426)**	**Proposed Device SIGNA™ Champion (K233728)**	**Comments**
Magnet	1.5T Superconducting Magnet with active shielding		SIGNA™ Champion uses the same magnet as the predicate SIGNA™ Voyager, with a modified enclosure design.
Gradient Subsystem	Water cooled gradient coil with active shielding.		SIGNA™ Champion uses the same gradient subsystem as the predicate SIGNA™ Voyager.

Subsystem or Component	Predicate Device SIGNA™ Voyager (K192426)	Proposed Device SIGNA™ Champion (K233728)	Comments
RF Transmit Subsystem	Transmit with integrated body coil and local T/R coil.		SIGNA™ Champion uses the same integrated body coil as the predicate SIGNA™ Voyager, but other components in the transmit chain are different. The SIGNA™ Champion uses the In Scan Room transmit architecture found in Reference Device 1 (SIGNA™ Victor).
RF Receive Subsystem	Digitize-Per-Pin (DPP) receive chain architecture.		SIGNA™ Champion uses the same DPP architecture as the predicate SIGNA™ Voyager.
RF Coils	Comprehensive suite of detachable coils for imaging all anatomies		Coils used by SIGNA™ Champion are also used by the predicate SIGNA™ Voyager and/or Reference Device 1 (SIGNA™ Victor).
Software Features	Comprehensive suite of software features, pulse sequences, and image processing applications to support MR imaging of all anatomies.		Both SIGNA™ Champion and the predicate SIGNA™ Voyager are fully capable MR systems with a wide range of software features. SIGNA™ Champion includes some new and enhanced features such as AIR Recon DL and Sonic DL that were not included in the predicate K192426 submission. The SIGNA™ Champion software features are similar to those found on Reference Device 2 (SIGNA™ Hero).
Gating Accessories	Respiratory, peripheral, and cardiac gating.	Respiratory peripheral and cardiac gating with wireless connection option.	In addition to SIGNA™ Voyager's gating solution, SIGNA™ Champion offers an additional option to use wireless connection.

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™ Champion compared to the predicate device.

Determination of Substantial Equivalence

Summary of Non-Clinical Tests:

The SIGNA™ Champion 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

In addition, the SIGNA™ Champion complies with applicable NEMA MS standards for MRI and NEMA PS3 standard for DICOM, as does the predicate device.

Both the SIGNA™ Champion 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™ Champion, 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™ Champion 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™ Champion 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™ Champion 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™ Champion is substantially equivalent to the predicate device to which it has been compared.

Conclusion

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