GE Healthcare (GE Medical Systems, LLC)
% Sandra Westphal
Regulatory Affairs Leader
3200 N Grandview Blvd.
WAUKESHA WI 53188

January 20, 2022

Re: K213668
Trade/Device Name: SIGNA Hero
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI
Dated: November 19, 2021
Received: November 22, 2021

Dear Sandra Westphal:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K213668

Device Name
SIGNA Hero

Indications for Use *(Describe)*

The SIGNA Hero 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 Hero 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.

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Section 5
510(K) Summary

510(k) Summary

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

Date:	Nov 19, 2021
Submitter:	GE Medical Systems, LLC 3200 N Grandview Blvd. Waukesha, WI USA 53188
Primary Contact Person:	Sandra Westphal Regulatory Affairs Leader GE Healthcare Phone: 262-720-8872 E-mail: Sandra.westphal@ge.com
Secondary Contact Person:	Glen Sabin Director, Regulatory Affairs GE Healthcare Phone: 262-521-6848 E-mail: glen.sabin@ge.com
Device Trade Name:	SIGNA™ Hero
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Classification Names:	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000
Product Code:	LNH, LNI
Predicate Device(s):	SIGNA™ Pioneer (K160621)
Device Description:	SIGNA™ Hero is a whole body magnetic resonance scanner designed to support high resolution, high signal to-noise ratio, and short scan times. The systems use 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 oblique planes, using various pulse sequences, imaging techniques and reconstruction algorithms. The system features a 3.0T superconducting magnet with 70cm bore size. The system is designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).
Indications for Use	The SIGNA™ Hero 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™ Hero 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™ Hero employs the same fundamental scientific technology as its predicate device. SIGNA™ Hero offers two magnet configurations, building on the 3.0T 3TLC magnet, and introducing the newly designed 3.0T ARES (Platform) magnet. SIGNA™ Hero builds on the existing Gradient Driver design, RF transmit architecture design, RF receive chain design and software platform. SIGNA™ Hero offers a detachable eXpress patient table, similar to detachable tables available on other GEHC 3T MR systems.

Comparison of Indications for Use	The changes in technology do not impact the indications for use. The indications for use have not changed, other than to reflect the SIGNA™ Hero 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™ Hero employs the same fundamental scientific technology as the predicate device. **System Design:** There are one notable technological difference between the SIGNA™ Hero and the predicate device: the 3.0T ARES (Platform) magnet. **Operating Principles:** The SIGNA™ Hero functions using the same operating principles as the predicate device. **Materials:** The SIGNA™ Hero and the predicate device both use flame retardant materials. **Safety and Performance Testing:** Both the SIGNA™ Hero 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™ Hero compared to the predicate device.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The SIGNA™ Hero 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 • ISO 10993-1 • IEC 62464-1 In addition, the SIGNA™ Hero complies with applicable NEMA MS 3, NEMA MS 4, NEMA MS 8, and the NEMA PS3 standard for DICOM, as does the predicate device. Both the SIGNA™ Hero and the predicate device have a successful biocompatibility track record, as demonstrated by ISO 10993-1 testing and by the patient contacting materials' 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) <u>Summary of Clinical Tests:</u> The subject of this premarket submission, the SIGNA™ Hero, 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™ Hero in accordance with the FDA Guidance "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" issued on November 18, 2016. The image quality of the SIGNA™ Hero 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™ Hero 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™ Hero is substantially equivalent to the predicate device to which it has been compared.
Conclusion:	In conclusion, GE Healthcare considers the SIGNA™ Hero to be as safe, as effective, with performance that is substantially equivalent to the predicate device.