**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GE Healthcare (GE Medical Systems, LLC)
% Mr. Glen Sabin
Regulatory Affairs Director
3200 N. Grandview Blvd.
WAUKESHA WI 53188

February 4, 2015

Re: K143251
Trade/Device Name: 1.5T SIGNA Creator and 1.5T SIGNA Explorer
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 7, 2014
Received: November 12, 2014

Dear Mr. 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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)* K143251

Device Name
1.5T SIGNA Creator and 1.5T SIGNA Explorer

Indications for Use *(Describe)*
1.5T SIGNA Creator and 1.5T SIGNA Explorer 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 1.5T SIGNA Creator and 1.5T SIGNA Explorer reflects 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.**

## 510(k) Summary

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

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| Date: | November 7, 2014 |
| Submitter: | GE Healthcare (GE Medical Systems, LLC)<br>3200 N. Grandview Blvd.,<br>Waukesha, WI 53188<br>USA |
| Primary Contact Person: | Glen Sabin<br>Regulatory Affairs Director<br>GE Healthcare<br>Phone: 262-521-6848<br>Fax: 262-364-2785 |
| Secondary Contact Person: | Ruoqian Liu<br>Regulatory Affairs Director<br>GE Healthcare<br>Phone: 86-10-58068943<br>Fax: 86-10-67803267 |
| Device: Trade Name: | 1.5T SIGNA Creator, 1.5T SIGNA Explorer |
| Common/Usual Name: | Magnetic Resonance Imaging System |
| Classification Names: | Magnetic resonance diagnostic device |
| Product Code: | LNH |
| Predicate Device(s): | 1.5T Brivo MR355 and 1.5T Optima MR360 (K123417)<br>1.5T Optima MR450w (K142085) |
| Device Description: | 1.5T SIGNA Creator and 1.5T SIGNA Explorer is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. The 1.5T SIGNA Creator and 1.5T SIGNA Explorer features a superconducting magnet operating at 1.5 Tesla. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of nuclei exhibiting magnetic resonance. The data acquisition system accommodates 16 independent receive channels and multiple independent coil elements per channel during a single acquisition series. |

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| Intended Use: | 1.5T SIGNA Creator and 1.5T SIGNA Explorer 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.<br><br>The images produced by 1.5T SIGNA Creator and 1.5T SIGNA Explorer 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: | Proposed 1.5T SIGNA Creator and 1.5T SIGNA Explorer employs the same fundamental scientific technology as its predicate device 1.5T Brivo MR355 and 1.5T Optima MR360 (K123417). |
| Determination of Substantial Equivalence: | Summary of Non-Clinical Tests:<br><br>1.5T SIGNA Creator and 1.5T SIGNA Explorer and its applications underwent testing to comply with voluntary standards, including IEC60601-1, IEC60601-2-33, IEC60601-1-1, IEC60601-1-2. In addition, the following FDA-recognized performance standards were used to test the 1.5T SIGNA Creator and 1.5T SIGNA Explorer: NEMA MS1, MS2, MS3, MS4, MS5 and MS8. Additionally, the communication interface for the 1.5T SIGNA Creator and 1.5T SIGNA Explorer is designed to support DICOM format as defined in the NEMA PS PS3.1-3.20 set of standards. The predicate devices also complied with these standards.<br><br>As with the predicate devices, 1.5T SIGNA Creator and 1.5T SIGNA Explorer applied the following quality assurance measures:<br>• Risk Analysis<br>• Requirements Reviews<br>• Design Reviews<br>• Testing on unit level (Module verification)<br>• Integration testing (System verification) |

- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, 1.5T SIGNA Creator and 1.5T SIGNA Explorer did not require clinical studies to support substantial equivalence. Internal scans were conducted as part of validation for workflow and image quality, and sample clinical images are included in the submission.

Substantial Equivalence Conclusion:

The indications for use of the proposed systems and the predicates are nearly identical. The name of the device has changed and minor updates were made to the feature set. 1.5T SIGNA Creator and 1.5T SIGNA Explorer employs equivalent technology to the reference devices. Additionally, the result of the above described testing demonstrates that the device performs as intended.

Conclusion: GE Healthcare considers the 1.5T SIGNA Creator and 1.5T SIGNA Explorer to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).