GE Healthcare
510(k) Premarket Notification Submission

SEP 20 2012

510(k) Summary

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

Date:	25-May-2012
Submitter:	GE Healthcare, (GE Medical Systems LLC) 3200 N Grandview Blvd, Waukesha, WI 53188 USA
Primary Contact Person:	Shashidhar C S Regulatory Affairs Leader - MR GE Healthcare, Phone: +91-80-40883613
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director - MR GE Healthcare, Phone: (262) 521-6848 Fax: (262) 364-2785
Device / Trade Name:	1.5T Signa HDx family and 3.0T Signa HDx family
Common /Usual Name:	Magnetic Resonance Imaging System
Classification Names:	Magnetic resonance diagnostic device
Product Code:	LNH
Predicate Device(s):	1.5T and 3.0T Signa HDx MR System (K052293) Discovery MR750w 3.0T (K103327)
Device Description:	The 1.5T Signa HDx family and 3.0T Signa HDx family systems are a whole body magnetic resonance system designed to support high resolution, high signal-to-noise ratio, and short scan times. The Signa HDx family of scanners is available in two different field strengths of 1.5T and 3.0T. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. The data acquisition system accommodates up to 32 independent receive channels in various increments and multiple

independent coil elements per channel during a single acquisition series. The System can image axial, sagittal, coronal, and oblique anatomical images, spectroscopic data, parametric maps, or dynamic images of the structures or functions of the entire body.

Intended Use:

The 1.5T Signa HDx family and 3.0T Signa HDx family are 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 1.5T Signa HDx family and 3.0T Signa HDx family 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.

Technology:

The 1.5T Signa HDx family and 3.0T Signa HDx family employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The 1.5T Signa HDx family and 3.0T Signa HDx family and its applications comply with voluntary standards, including IEC60601-1, IEC60601-2-33, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, IEC60601-1-6, ISO14971, ISO10993-1 and IEC62304.

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- 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 HDx family and 3.0T Signa HDx family did not require external clinical studies to support substantial equivalence. Internal scans were conducted as part of validation for workflow and image quality and that sample clinical images are included in the submission.

Conclusion:

GE Healthcare considers the 1.5T Signa HDx family and 3.0T Signa HDx family to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SEP 20 2012

Mr. C.S. Shashidhar
Regulatory Affairs Leader
GE Medical Systems LLC
3200 N. Grandview Blvd
WAUKESHA WI 53188

Re: K121676
Trade/Device Name: 1.5T Signa HDx family and 3.0T Signa HDx family
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, MOS, and LNI
Dated: September 7, 2012
Received: September 11, 2012

Dear Mr. Shashidhar:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K121676

Device Name: 1.5T Signa HDx family and 3.0T Signa HDx family

Indications for Use:

The 1.5T Signa HDx family and 3.0T Signa HDx family are 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 1.5T Signa HDx family and 3.0T Signa HDx family 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.

Prescription Use __X__	AND/OR	Over-The-Counter Use____
(Part 21 CFR 801 Subpart D)		(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121676