



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Ge Medical Systems, LLC  
Glen Sabin  
Regulatory Affairs Director  
3200 Grandview Blvd  
Waukesha, Wisconsin 53188

April 20, 2017

Re: k162722

Trade/Device Name: HyperSense  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic Resonance Diagnostic Device  
Regulatory Class: Class II  
Product Code: LNH  
Dated: March 15, 2017  
Received: March 16, 2017

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 (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,

A handwritten signature in blue ink that reads "Robert A. Ochs, Ph.D.". The signature is written in a cursive style and is positioned over a faint, semi-transparent watermark of the FDA logo.

FOR

Robert A. Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K162722

Device Name

HyperSense

Indications for Use (Describe)

HyperSense is a software feature intended for use on GE MR 1.5T and 3.0T Systems. HyperSense is an acceleration technique based on sparse data sampling and iterative reconstruction that allows users to reduce scan times or increase scan resolution. HyperSense can be used for non-contrast enhanced imaging of the head, neck, spine, extremities, pelvis, and abdomen.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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GE Healthcare  
510(k) Premarket Notification Submission

In accordance with 21 CFR 807.92 the following summary of information is provided:	
<u>Date:</u>	19 April 2017
<u>Primary Contact Person:</u>	Glen Sabin Regulatory Affairs Director, MR GE Healthcare, (GE Medical Systems, LLC) Phone: 262-521-6848 Fax: 414-908-9585
<u>Secondary Contact Person:</u>	James McMahon Senior Director, Regulatory Affairs – MR GE Healthcare, (GE Medical Systems, LLC) Phone: 508-382-2858
<u>Device Trade Name:</u>	HyperSense
<u>Common/Usual Name:</u>	Magnetic Resonance Diagnostic Device
<u>Classification Names:</u>	892.1000
<u>Product Code:</u>	LNH
<u>Predicate Devices:</u>	Predicate Device: ARC (K142085)
<u>Device Description:</u>	<p>HyperSense is a software feature used on GE 1.5T and 3.0T MR systems.</p> <p>HyperSense is an acceleration technique based on sparse data sampling and iterative reconstruction, enabling faster imaging without the penalties commonly found with conventional parallel imaging.</p> <p>HyperSense is intended to be used with volumetric acquisitions, and can be combined with other methods of acceleration (ARC) for achieving high signal to noise ratio with shorter acquisition times. HyperSense can deliver higher spatial resolution images or reduced scan times.</p>



GE Healthcare  
510(k) Premarket Notification Submission

<u>Indications for Use:</u>	<p>HyperSense is a software feature intended for use on GE MR 1.5T and 3.0T Systems. HyperSense is an acceleration technique based on sparse data sampling and iterative reconstruction that allows users to reduce scan times or increase scan resolution. HyperSense can be used for non-contrast enhanced imaging of the head, neck, spine, extremities, pelvis, and abdomen.</p>
<u>Comparison of Intended Use</u>	<p>Both HyperSense and the predicate device are magnetic resonance imaging devices intended for diagnostic use.</p> <p>Both indications for use statements are functional in nature, and do not list specific diseases or conditions. HyperSense and the predicate device are indicated for the same patient population, and for the same clinical setting. Both indications for use statements include a range of intended anatomies.</p> <p>Therefore, GE Healthcare believes that HyperSense 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.</p>
<u>Comparison of Technological Characteristics:</u>	<p>The most notable technological difference between HyperSense and the predicate device is that HyperSense adopts compressed sensing acquisition method based on sparse data compressibility allowing scan time reduction while maintaining appropriate image quality.</p> <p>Per bench and clinical data collected to validate the indications for use, this technological difference does not raise any different questions of 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 HyperSense compared to the predicate device</p>



GE Healthcare  
510(k) Premarket Notification Submission

<p><u>Performance Data</u></p>	<p><u>Summary of Non-Clinical Tests:</u> HyperSense is a software only feature and complies with the following voluntary standards:</p> <ul style="list-style-type: none"><li>• AAMI/ANSI 62304</li><li>• AAMI/ANSI ES60601-1</li><li>• IEC 60601-2-33</li></ul> <p>In addition, HyperSense complies with NEMA PS3.1-3.18 for DICOM conformance.</p> <p>HyperSense complies with the same applicable standards as the software used in the predicate device.</p> <p>As with the predicate device, the following quality assurance measures were applied to the development of HyperSense:</p> <ul style="list-style-type: none"><li>• Risk Analysis</li><li>• Requirements Reviews</li><li>• Design Reviews</li><li>• Testing on unit level (Module verification)</li><li>• Integration testing (System verification)</li><li>• Performance testing (Verification)</li><li>• Safety testing (Verification)</li><li>• Simulated use testing (Validation)</li></ul> <p>Phantom testing has been conducted to evaluate the impact of HyperSense on Signal to Noise Ratio (SNR), and spatial resolution.</p> <p>The non-clinical testing was completed with passing results per the pass/fail criteria defined in the test cases.</p> <p><u>Summary of Clinical Tests:</u> A clinical study has been performed to evaluate the impact of HyperSense on image quality, as measured by the legibility of morphological features. Additionally, a peer reviewed journal article describing a study of the HyperSense technique has been provided in this submission as supporting evidence. The clinical results demonstrated that HyperSense maintains comparable imaging performance results as its predicate devices (K142085). Sample clinical images are included in this submission.</p>
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**GE Healthcare**  
510(k) Premarket Notification Submission

<p><u>Conclusion:</u></p>	<p>GE Healthcare believes that the HyperSense software feature has substantially the same intended use as the predicate ARC. This 510(k) submission includes information on the technological characteristics of the HyperSense feature, as well as performance data demonstrating that HyperSense is as safe and effective as the predicate, and does not raise different questions of safety and effectiveness.</p> <p>In conclusion, GE Healthcare believes that the HyperSense feature is substantially equivalent to the predicate device.</p>
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