



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

GE Medical Systems, LLC  
Mary Mayka  
Regulatory Affairs Manager  
3200 Grandview Blvd  
WAUKESHA WI 53188

August 31, 2016

Re: K161397  
Trade/Device Name: MAGiC  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance diagnostic device  
Regulatory Class: II  
Product Code: LNH  
Dated: July 29, 2016  
Received: August 1, 2016

Dear Dr. Mayka:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

For

Robert 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)

K161397

Device Name

MAGiC

Indications for Use (Describe)

MAGiC (MAGnetic resonance image Compilation) is a software option based on a combination of acquisition and post processing software that is intended for use on GE imaging platforms. MAGiC generates multiple image contrasts from a single acquisition scan. MAGiC enables post-acquisition image contrast adjustment. MAGiC also allows for the generation of parametric maps for further analysis of MRI acquisition data. MAGiC is indicated for head imaging.

When interpreted by a trained physician, MAGiC images can provide information useful in determining 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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GE Healthcare  
510(k) Premarket Notification Submission

510(k) Summary

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

<u>Date:</u>	July 28, 2016
<u>Submitter:</u>	GE Medical Systems, LLC (GE Healthcare) 3200 N. Grandview Blvd., Waukesha, WI 53188 USA
<u>Primary Contact Person:</u>	Mary A. Mayka, Ph.D. Regulatory Affairs Manager GE Healthcare Phone: 262-527-3148 Fax: 262-364-2785
<u>Secondary Contact Person:</u>	Glen Sabin Regulatory Affairs Director GE Healthcare Phone: 262-521-6848 Fax: 262-364-2785
<u>Device Trade Name:</u>	MAGiC (MAGnetic resonance image Compilation)
<u>Common/Usual Name:</u>	Magnetic Resonance Diagnostic Device
<u>Classification Names:</u>	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000
<u>Product Code:</u>	LNH
<u>Predicate Device(s):</u>	Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, Optima MR450w 1.5T (K142085)



## GE Healthcare

510(k) Premarket Notification Submission

<p><u>Device Description:</u></p>	<p>MAGiC (MAGnetic resonance image Compilation) allows the user to generate multiple contrasts in a single scan. MAGiC utilizes a multi-delay, multi-echo acquisition (MDME). The data acquired is processed using a technique to generate multiple image contrasts simultaneously, such as T1, T2, PD and Inversion Recovery (IR) weighted images (including: T1-FLAIR, T2-FLAIR, STIR, Double IR and PSIR weighted images). MAGiC generates all the different image contrasts from the same acquisition, leading to enhanced image slice registration, owing to the absence of inter-acquisition patient movement. MAGiC provides the user the ability to change the contrast of the images after acquisition. This is performed by adjusting the TR, TE, and/or TI parameters post-acquisition, to generate the specific contrast desired. MAGiC also enables users to generate parametric maps, such as T1, T2, R1, R2, PD, for further analysis of MRI acquisition data.</p>
<p><u>Intended Use:</u></p>	<p>MAGiC (MAGnetic resonance image Compilation) is a software option based on a combination of acquisition and post processing software that is intended for use on GE imaging platforms. MAGiC generates multiple image contrasts from a single acquisition scan. MAGiC enables post-acquisition image contrast adjustment. MAGiC also allows for the generation of parametric maps for further analysis of MRI acquisition data. MAGiC is indicated for head imaging.</p> <p>When interpreted by a trained physician, MAGiC images can provide information useful in determining diagnosis.</p>
<p><u>Technology:</u></p>	<p>MAGiC employs the same fundamental scientific technology as its predicate devices.</p>



## GE Healthcare

510(k) Premarket Notification Submission

<p><u>Determination of Substantial Equivalence:</u></p>	<p><u>Summary of Non-Clinical Tests:</u> MAGiC 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, MAGiC complies with NEMA PS3.1-3.18 for DICOM conformance.</p> <p>The following quality assurance measures were applied to the development of the device:</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>The non-clinical tests have been summarized in the verification and validation testing for MAGiC. The testing was completed with passing results per the pass/fail criteria defined in the test cases. This supports substantial equivalence to its predicates because it was also developed under quality assurance Design Controls. In addition, the software complies with the same applicable Standards.</p> <p><u>Summary of Clinical Tests:</u> A reader study was conducted to demonstrate acceptable diagnostic image quality and equivalent radiologic finding classes compared to the predicate device.</p>
<p><u>Conclusion:</u></p>	<p>GE Healthcare considers MAGiC to be as safe, as effective, and performance is substantially equivalent to the predicate devices.</p>