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

July 29, 2015

GE Medical Systems, LLC
% Ms. Jenny Wong
Regulatory Affairs Leader, Magnetic Resonance
3200 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K143368
Trade/Device Name: GenIQ
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 7, 2015
Received: July 8, 2015

Dear Ms. Wong:

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,

For

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)*
K143368

Device Name
GenIQ

Indications for Use *(Describe)*
GenIQ is an automated post-processing software option that is indicated for use on dynamic magnetic resonance imaging data sets to generate parametric images from the image intensity variations over time. This dynamic change in signal intensity is used to calculate functional parameters related to tissue flow and leakage of the contrast agent from the intravascular to the extracellular space.
GenIQ provides information that when interpreted by a trained physician, can be useful for assessing tissue vascular properties.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 5: 510(k) Summary

GenIQ

510(k) Summary

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

Date: November 24, 2014

Submitter: GE Medical Systems SCS
283 Rue de la Miniere
Buc, France 78530
FDA Registration Number: 9611343

Primary Contact Person: Jenny Wong
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Device: Trade Name: GenIQ

Common/Usual Name: System, image processing, radiological- Picture archiving and communications system.

Classification Names: 21CFR 892.2050

Product Code: LLZ

Predicate Device(s):	Predicate Device Name: MR Permeability Software Predicate 510k Number: K130278 Predicate Manufacturer: Philips Medical Systems Nederland B.V.
Device Description:	GenIQ is a software application used for the pharmacokinetic analysis of Dynamic Contrast Enhanced (DCE) MRI data sets. The application is used to perform a General Kinetic Model (GKM)–based pharmacokinetic modeling of DCE-MRI data. The goal of GenIQ is to extract functional parameters describing tissue vascular properties such as forward and backward transfer constants, plasma volume, and volume of extra-cellular space.
Indications for Use:	GenIQ is an automated post-processing software option that is indicated for use on dynamic magnetic resonance imaging data sets to generate parametric images from the image intensity variations over time. This dynamic change in signal intensity is used to calculate functional parameters related to tissue flow and leakage of the contrast agent from the intravascular to the extracellular space. GenIQ provides information that when interpreted by a trained physician, can be useful for assessing tissue vascular properties.
Comparison of Technological Characteristics with Predicate Device:	The proposed medical device, GenIQ, employs the same fundamental scientific technology as its predicate device, MR Permeability. The proposed device (GenIQ) is substantially equivalent to the predicate device because it is a post-processing software option for use on dynamic contrast enhanced (DCE) MR image datasets.

Determination of Substantial Equivalence:

Summary of Non-Clinical and Clinical Tests:

The GenIQ and its applications comply with voluntary standards:

- ISO 13485
- ISO 14971
- IEC 62304
- IEC 62366

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)

Simulated use testing was performed on digital phantom data referenced by Quantitative Imaging Biomarkers Alliance (QIBA). This validation demonstrated good implementation of the General Kinetic Model. In addition, anonymized MR contrast-enhanced images were used as clinical datasets to validate the GenIQ application.

Conclusion: GE Healthcare considers the GenIQ application to be as safe, as effective, and performance is substantially equivalent to the predicate device.