K123417

JAN 17 2013

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

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

Date:	10 October 10, 2012
Submitter:	GE Healthcare, (GE Hangwei Medical Systems Co., Ltd.) No.2 Yong Chang North Road, Beijing Economic & Tech Development Area Beijing, 100176, China
Primary Contact Person:	Ruoqian Liu Regulatory Affairs Manager GE Healthcare Phone: 86-10-58068943 Fax: 86-10-67803267
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director GE Healthcare Phone: 262-521-6848 Fax: 262-364-2785
Device: Trade Name:	1.5T Brivo MR355 and 1.5T Optima MR360
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 (K103330) Discovery MR750w 3.0T (K103327)
Device Description:	1.5T Brivo MR355 and 1.5T Optima MR360 is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. The 1.5T Brivo MR355 and 1.5T Optima MR360 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.

Intended Use: 1.5T Brivo MR355 and 1.5T Optima MR360 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 Brivo MR355 and 1.5T Optima MR360 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 Brivo MR355 and 1.5T Optima MR360 employs the same fundamental scientific technology as its predicate device 1.5T Brivo MR355 and 1.5T Optima MR360 (K103330).

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

1.5T Brivo MR355 and 1.5T Optima MR360 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.

- 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 Brivo MR355 and 1.5T Optima MR360 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.

Conclusion: GE Healthcare considers the 1.5T Brivo MR355 and 1.5T Optima MR360 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 Center – WO66-G609
Silver Spring, MD 20993-002

GE Hangwei Medical Systems Co., Ltd
% Ruoqian Liu
Regulatory Affairs Manager
No2 Yong Chang North Road
Beijing Economic & Tech Development Area
Beijing, 100176, CHINA

January 17, 2013

Re: K123417
Trade/Device Name: 1.5T Brivo MR355 and 1.5T Optima MR360
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: November 1, 2012
Received: November 6, 2012

Dear Mr. Liu:

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 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health 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,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

GE Healthcare
510(k) Premarket Notification Submission

510(k) Number (if known):

Device Name: 1.5T Brivo MR355 and 1.5T Optima MR360

Indications for Use:

1.5T Brivo MR355 and 1.5T Optima MR360 are whole body magnetic resonance scanners 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 Brivo MR355 and 1.5T Optima MR360 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.

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 Diagnostics and Radiological Health (OIR)

Michael D. O'Hara
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

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