K113394

510(k) Summary

DEC 1 1 2012

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

Date:	November 09, 2011
Submitter:	GE Healthcare (GE Medical Systems, LLC) 3200 N. Grandview Blvd. Waukesha, WI 53188 USA
Primary Contact Person:	Yuan Ma Regulatory Affairs Leader GE Healthcare (GE Medical Systems, LLC) (262) 521-6223 (414) 908-9390fax
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director GE Healthcare (GE Medical Systems, LLC) (262) 521-6848 (262) 521-6439 fax
Device: Trade Name:	MAVRIC SL
Common/Usual Name:	Software Option for Magnetic Resonance Imaging System
Classification Names:	21 C.F.R. 892.1000 Magnetic Resonance Diagnostic Device
Product Code:	LNH
Predicate Device(s):	PROPELLER Imaging Option for MRI, K031230
Device Description:	MAVRIC SL is a software application offered as an option for GE MR scanners. MAVRIC SL is based upon conventional 2D-FSE and then adds view-angle-tilting and additional phase-encoding in the slice-selective dimension. As a result, MAVRIC SL has reduced image artifacts and provides adequate spectral coverage in the presence of metal implants.

Intended Use: MAVRIC SL is a combination of an acquisition technique and post-processing software intended for use on GE 1.5T and 3.0T MR systems. MAVRIC SL is suitable for use on all patients cleared for MR exams.
MAVRIC SL helps reduce artifacts caused by presence of metal in both in-plane and through-plane dimensions compared to conventional MR imaging techniques. Thus MAVRIC SL allows visualizing tissue in the vicinity of implanted metal instrumentation.
When interpreted by a trained physician, images generated by MAVRIC SL provide information that can be useful in determining a diagnosis.

Technology: MAVRIC SL is an FSE-based, 3D Multi-Spectral Imaging technique. Individually encoded spectral images in the MAVRIC SL technique overlap in the frequency domain and together span a wide spectrum of spins located near metal implants. MAVRIC SL generates a final image by combining the individually encoded spectral images in a post-processing step.

MAVRIC SL software option employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MAVRIC SL software option complies with voluntary standards as detailed in Section 9, 11, 16 and 18 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- ✓ Risk Analysis
- ✓ Requirements Reviews
- ✓ Design Reviews
- ✓ Design Verification
- ✓ Safety Testing

The following safety parameters were measured:

- ✓ Acoustic Noise
- ✓ dB/dt
- ✓ SAR

The non-clinical tests outlined above have been executed with acceptable results. Refer to Sections 9, 16, and 18 of this submission for testing results.

Summary of Clinical Tests:

The following clinical testing has been performed to validate the MAVRIC SL technique:

- ✓ Application validation
- ✓ Clinical imaging

Conclusion: GE Healthcare considers the MAVRIC SL software option to be as safe, as effective, and performance is substantially equivalent to the predicate device.

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

December 11, 2012

GE Medical System, LLC
C/O Mr. Yuan Ma
Regualtory Affairs Leader, MR
3200 N. Grandview Blvd. W-828
WAUKESHA, WI 53188

Re: K113394
Trade/Device Name: MAVRIC SL
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 8, 2012
Received: November 9, 2012

Dear Mr. Ma:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
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): K113394

Device Name: MAVRIC SL

Indications for Use:

MAVRIC SL is a combination of an acquisition technique and post-processing software intended for use on GE 1.5T and 3.0T MR systems. MAVRIC SL is suitable for use on all patients with passive MR Conditional orthopedics implants that are scanned according to the conditions of safe use for the specific MR Conditional implant being scanned. In addition, MAVRIC SL is suitable for use on patients without implants that are cleared for MR exams.

MAVRIC SL helps reduce artifacts caused by presence of metal in both in-plane and through-plane dimensions compared to conventional MR imaging techniques. Thus MAVRIC SL allows visualizing more tissue in the vicinity of MR Conditional implanted metal instrumentation.

When interpreted by a trained physician, images generated by MAVRIC SL provide information that can be useful in determining a diagnosis.

Prescription Use __X__ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

Janine M. Morris -S
2012.12.12 08:02:20 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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