K123068

NOV 1 3 2012

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:	September 19, 2012
Submitter:	GE Medical Systems, LLC (GE Healthcare) 301 Ballardvale Street, Suite 4 Wilmington, MA 01887
Primary Contact Person:	Yuan Ma Regulatory Affairs Manager GE Medical Systems, LLC (GE Healthcare) Tel: (781) 262-5581 Fax: (414) 908-9390 yuan.ma@med.ge.com
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director GE Healthcare (GE Medical Systems, LLC) (262) 521-6848 (262) 364-2785 Glen.Sabin@med.ge.com
Establishment Registration Number:	3008193097
Device Trade Name:	Optima MR430s
Common/Usual Name:	Magnetic Resonance Imaging System
Classification Names:Product Code:	21 C.F.R. 892.1000 Magnetic Resonance Diagnostic Device LNH
Predicate Device(s):	K103238, Optima MR430s MRI Scanner
Device Description:	The Optima MR430s MRI Scanner utilizes a superconducting magnet to acquire 2D single-slice and multi-slice and 3D volume images. A wide variety of pulse sequences are provided to the operator, including spin echo, fast spin echo, 2D and 3D gradient echo acquisitions. Imaging options such as inversion recovery, flow compensation and fat/water suppression are provided to suppress artifacts due to physiological motion and improve image quality. The system is used as a stationary system.

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Intended Use: The Optima MR430s MRI Scanner is indicated to use as a magnetic resonance imaging device of the leg (excluding the thigh), knee, ankle, foot, elbow, forearm, wrist, and hand. The device produces transverse, sagittal, coronal, and oblique cross-sectional images, displaying the internal structure of the limbs and joints being imaged. If interpreted by a medical expert, these images can provide diagnostically useful information.

Technology: The modified Optima MR430s employs the same fundamental scientific technology as the unmodified predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Optima MR430s complies with voluntary standards as detailed in Sections 9 of this premarket submission. The following quality assurance measures were applied to the modification of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance Testing (Verification)
- System Validation Testing

Summary of Clinical Tests:

The modification that prompted this submission did not require clinical testing.

Conclusion: GE Healthcare considers the Optima MR430s 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

GE Medical Systems, LLC
Speciality MR
301 Ballardvale Street
Suite 4
Wilmington, MA 01887

NOV 1 3 2012

Re: K123068
Trade/Device Name: OPTIMA MR430s
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: October 01, 2012
Received: October 16, 2012

Dear Dr. 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.

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
2012.11.09 15:33:15 -05'00'

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

Enclosure

510(k) Number (if known): K123068

Device Name: Optima MR430s

Indications for Use:

The Optima MR430s MR Scanner is indicated to use as a magnetic resonance imaging device of the leg (excluding the thigh), knee, ankle, foot, elbow, forearm, wrist, and hand. The device produces transverse, sagittal, coronal, and oblique cross-sectional images, displaying the internal structure of the limbs and joints being imaged. If interpreted by a medical expert, these images can provide diagnostically useful information.

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 Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) 123068

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