K103238

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GE Healthcare
301 Ballardvale Street
Wilmington, MA 01887

510(k) Summary

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

Date: October 29, 2010

Submitter: GE Medical Systems, LLC (GE Healthcare)
301 Ballardvale Street, Suite 4
Wilmington, MA 01887

Primary Contact Person: Norma LeMay
Regulatory Affairs Leader, Specialty MR
GE Medical Systems, LLC (GE Healthcare)
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Secondary Contact Person: Glen Sabin
Director of Regulatory Affairs, MR
GE Medical Systems, LLC (GE Healthcare)
3200 N Grandview Boulevard
Waukesha, WI 53188
Tel: (262) 521-6848
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Device: Trade Name: Optima MR430s MRI Scanner

Common/Usual Name: Magnetic Resonance Diagnostic Device

Classification Names: Magnetic Resonance Diagnostic Device

Product Code: LNH

Predicate Device(s): K080048, MSK Extreme 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.

Indications for 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 Optima MR430s employs the same fundamental scientific technology as its predicate device (MSK Extreme, K080048).

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Optima MR430s complies with voluntary standards as detailed in Sections 9 and 17 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 Testing
- System Verification Testing
- Performance testing (Verification)
- Safety testing (Verification)

The results of all testing performed indicate that the Optima MR430s meets the acceptance criteria and is substantially equivalent to the currently cleared 1.5T MSK Extreme (predicate device, cleared through K080048).

Summary of Clinical Tests:

As part of Verification testing, a non-significant risk study was performed to characterize onset levels for Peripheral Nerve Stimulation (PNS) in accordance with IEC 60601-2-33 for the

change in the gradient slew rate (300 T/m/s). No nerve sensation was reported. As a result, with respect to PNS, the system is not capable of operating outside of the Normal Operating Mode.

The sample DICOM images included in this submission were also collected as part of a non-significant risk study.

See Section 20 for more details of the studies performed.

Conclusion: GE Healthcare considers the Optima MR430s 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
Silver Spring, MD 20993

Ms. Norma J. LeMay
Regulatory Affairs Leader
GE Healthcare
301 Ballard Street, Suite 4
WILMINGTON MA 01887

FEB 25 2011

Re: K103238
Trade/Device Name: Optima MR430s 1.5T MR Scanner
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: January 31, 2011
Received: February 1, 2011

Dear Ms. LeMay:

This letter corrects our substantially equivalent letter of February 11, 2011.

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 (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 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,

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

510(k) Number (if known): K103238

Device Name: Optima MR430s 1.5T MR Scanner

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)

Mary S Pastel

Division Sign-off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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