K091536

JUL 17 2009

GE Healthcare

3200 N. Grandview Blvd.
Waukesha, WI 53188
USA

Section 5 – 510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Submitter: GE Healthcare
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Date Prepared: 15 May 2009

Device Name:

Proprietary Name: Optima MR450w
Classification Name: Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

Predicate Device:
GE Discovery® MR450 System (K083147)

Device Description:

The 1.5T GE Optima MR450w features a superconducting magnet operating at 1.5 Tesla. The data acquisition system accommodates up to 32 independent receive channels in various increments, and multiple independent coil elements per channel during a single acquisition series. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences and reconstruction algorithms.. The 1.5T GE Optima MR450w is designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).

Indications for Use:

The Optima MR450w is a whole body magnetic resonance scanner designed to support high resolution and high signal-to-noise ratio images in short exam times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique anatomical images, spectroscopic data, parametric maps, , or dynamic images of the structures or functions of the entire body. The indication for use includes, but is 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 Optima MR450w reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and spectra, when interpreted by a trained physician yield information that may assist in diagnosis.

Comparison with Predicate Devices:

The indications for use for the Optima MR450w System are similar to those for the GE Discovery® MR450 System.

Comparison statement between Optima MR450w and Discovery MR450 System :

The GE Optima MR450w is a new device design that is similar to the previously cleared 1.5T HDx MR system (K052293) with the main difference being the static magnet physical dimensions, which reflect the design objective of creating a larger diameter patient enclosure (bore). Both systems utilize superconducting magnets, gradients, and radio frequency coils and electronics to acquire data in single voxel, two-dimensional, or three-dimensional datasets. The operating software is common to both systems, as are the user applications provided with the system or offered as options.

Summary of Studies:

As stated in the FDA document "Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" the following parameters have been measured

and documented through testing to NEMA, IEC or ISO standards (as referenced throughout this submission and listed in Section 9:

Performance:

Signal-to-noise ratio (SNR)
Geometric distortion
Image uniformity
Slice thickness
Spatial resolution

Safety

Static field strength
Acoustic noise
dB/dt
RF heating (SAR)
Biocompatibility

The Optima MR450w has been designed to comply with applicable IEC standards. It shall be certified by a Nationally Recognized Testing Laboratory to conform to IEC, UL and CSA standards prior to commercialization of the system.

Conclusion:

It is the opinion of GE that the GE Optima MR450w 1.5T system is substantially equivalent to the Discovery MR450 1.5T system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

GE Medical Systems LLC
% Mr. Daniel W. Lehtonen
Senior Staff Engineer-Medical Devices
Intertek Testing Services NA, Inc.
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

JUL 17 2009

Re: K091536
Trade/Device Name: Optima MR 450w
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: July 2, 2009
Received: July 6, 2009

Dear Mr. Lehtonen:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091536

Device Name: Optima MR450w

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Prescription Use X **AND/OR** **Over-the-Counter Use** _____
(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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091536