K102155

AUG 31 2010

510(k) Summary

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

Date:	July 28, 2010
Submitter:	GE Healthcare (GE Medical Systems, LLC) 3200 N. Grandview Blvd. Waukesha, WI 53188 USA
Primary Contact Person:	Tracey Fox Regulatory Affairs Manager GE Healthcare (GE Medical Systems, LLC) (262) 521-6079 (262) 521-6439
Secondary Contact Person:	Ayesha Pergadia RA Leader GE Healthcare (GE Medical Systems, LLC) (262) 521-6424 (262) 521-6439
Device: Trade Name:	MR Radiation Oncology Options
Common/Usual Name:	Patient Positioning Accessory for Magnetic Resonance Imaging System
Classification Names:	21 C.F.R. 892.1000 Magnetic Resonance Diagnostic Device
Product Code:	LNH
Predicate Device(s):	GE Signa® MR Oncology Package, K081916
Device Description:	The MR Radiation Oncology Options includes a radiation therapy insert that can be used with wide bore (70cm) GE MR scanners for radiation therapy planning. The MR Radiation Oncology Options is similar to the existing GE Signa®MR Oncology Package offered with GE Signa®MR Systems. MR Radiation Oncology Options utilizes a radiation therapy table insert that allows patients to be imaged on a flat surface that matches the imaging patient position. The MR Radiation Oncology Options may be used with MR compatible patient positioning accessories and a 3 pin Lok-Bar.

Intended Use:

The MR Radiation Oncology Options are a patient positioning package intended for use with the GE wide bore MR scanners. The MR Radiation Oncology Options when used with a GE wide bore MR scanner is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio and short scan times. The GE wide bore MR scanners with MR Radiation Oncology Options are indicated for use as a diagnostic imaging device to provide axial, sagittal, coronal, and oblique images, spectroscopic images, and/or spectra, dynamic images of the internal structures and organs 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. The images produced by the GE wide bore scanners with MR Radiation Oncology Options reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MR Radiation Oncology Options include a removable patient table insert for GE wide bore MR scanners that allow patients to be imaged on a flat surface. The flat patient surface allows image acquisition in patient positions similar to other modalities that also use a flat patient surface such as X-Ray, CT, PET, and radiation therapy. The GE wide bore MR scanners with the MR Radiation Oncology Options may also be used with MR-compatible patient positioning and immobilization accessories to assist in obtaining consistent patient positions throughout multiple imaging sessions.

Technology:

The MR Radiation Oncology Options employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MR Radiation Oncology Options and its applications comply with voluntary standards as detailed in Section 9, 11 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
- Subsystem Level Testing (Verification)
- Safety testing (Verification)

The non-clinical tests outlined above have been executed with acceptable results. Refer to Section 9.1 of this submission for safety testing and section 18 for verification testing.

Summary of Clinical Tests:

Simulated use testing was performed as part of the MR Radiation Oncology Package Design Validation. Clinical image comparisons demonstrate that the MR Radiation Oncology Options maintains the same imaging performance results as the GE Signa® MR Oncology Package with existing patient table.

Conclusion: GE Healthcare considers the MR Radiation Oncology Options 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 Room – WO66-G609
Silver Spring, MD 20993-0002

GE Medical System, LLC
3200 N. Grandview Blvd.
Waukesha, WI 53188
Attn: Tracey Fox

AUG 31 2010

Re: K102155
Trade/Device Name: MR Radiation Oncology Options
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH
Dated: July 28, 2010
Received: July 30, 2010

Dear Ms. Fox:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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* Diagnostic Device Evaluation and Safety 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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K102155

GE Healthcare

510(k) Premarket Notification Submission

510(k) Number (if known): K102155

Device Name: MR Radiation Oncology Options

Indications for Use

The MR Radiation Oncology Options are a patient positioning package intended for use with the GE wide bore MR scanners. The MR Radiation Oncology Options when used with a GE wide bore MR scanner is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio and short scan times. The GE wide bore MR scanners with MR Radiation Oncology Options are indicated for use as a diagnostic imaging device to provide axial, sagittal, coronal, and oblique images, spectroscopic images, and/or spectra, dynamic images of the internal structures and organs 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. The images produced by the GE wide bore scanners with MR Radiation Oncology Options reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

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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) K102155