K093689
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SUMMARY OF SAFETY AND EFFECTIVENESS

AUG 31 2010

Submitter's Name:	MR Medical Solutions
Submitter's Address:	310 Vista Park Drive, Pittsburgh PA 15205
Telephone number:	412-787-3454
Fax number:	412-787-3490
Official Correspondent:	Fahad Alradady
Date:	November 13, 2009
Trade/Proprietary Name:	1.5 Tesla 16-Channel Receive-only Phased-array Head Coil for Siemans
Common Name:	MR Imaging Surface Coil
Classification Number:	21 CFR 892.1000
Predicate Device:	1.5 Tesla 8-Receiver Neurovascular Coil, 510(k) number K023596

Substantial Equivalence: The information provided in this premarket notification demonstrates that the proposed device, the MR Medical Solutions 1.5 Tesla 16-Channel Receive-only Phased-array Head Coil, is substantially equivalent to a legally marketed predicate device, the Medrad 1.5 Tesla 8-Receiver Neurovascular Coil, when the Medrad device images a subset of the bodily regions it is intended to image; the proposed MR Medical Solutions device images the (a) intracranial/extracranial neurovasculature and (b) skull base, whereas the predicate device images the (a) intracranial/extracranial neurovasculature, (b) skull base and (c) C-spine.

The MR Medical Solutions device (1) maintains the same intended use for imaging the intracranial/extracranial neurovasculature and skull base of the predicate device, (2) has similar operational parameters, (3) has similar labeling and (4) is used in a manner similar to the predicate device.

The MR Medical Solutions 1.5 Tesla 16-Channel Receive-only Phased-array Head Coil is a receive-only coil intended to be used with 1.5T Siemens superconducting MRI scanners. The predicate device is a receive-only coil intended to be used with General Electric MRI Superconducting Scanner Systems.

Like the predicate device, the proposed device is indicated to be used only under the supervision of a physician or certified MR technologist who is trained in the field of Diagnostic Magnetic Resonance Imaging. Both devices are designed to be used with similar scanners for imaging similar regions of the body without moving the patient or the coil. No scan room intervention is required.

MR Medical Solutions has established, as part of its Quality System, design controls in compliance with FDA's Quality System Regulations (QSRs). These design controls were applied to the development of the 1.5 Tesla 16-Channel Receive-only Phased-array Head Coil and meet the requirements of the FDA's QSRs. Design verification and validation testing was performed as part of product development and in response to risk analysis.

Analysis of the collective set of data led to the conclusion that the MR Medical Solutions 1.5 Tesla 16-Channel Receive-only Phased-array Head Coil is substantially equivalent to the predicate device for its intended use when used as prescribed in the User Manual.

A comparison of features and principles of operation between the proposed device and predicate device is provided in the following table.

Feature	Predicate: Medrad 1.5 Tesla 8-Receiver Neurovascular Coil (K023596)	Proposed: 1.5 Tesla 16-Channel Receive-only Head Coil
Coil Type	Phased Array Receive-Only Coil	Phased Array Receive-Only Coil
Region of Interest	Vertex of the skull to the aortic arch	Head and base of skull
Compatibility	All phased array GEMS 1.5T Signa Excite platforms with 8-Receiver capability. All Signa System pulse sequences and appropriate imaging options.	1.5 Tesla Siemens Medical Systems MRI Scanner
Tuning	No external tuning, or matching, is necessary since the coil is matched to the recommended anatomy of interest.	No external tuning, or matching, is necessary since the coil is matched to imaging the head and skull base.
System connection	The coil plugs into the MRI System by way of the Phased Array quick disconnect port	The coil plugs into the MRI System by way of the Phased Array quick disconnect port.
Imaging configurations	High resolution Head, Parallel imaging Fast Brain, Neurovasculature, C-Spine (user optional), Volume Neck (user optional), High resolution Head and C-Spine (user optional)	High resolution of Head and skull base, and Parallel Imaging Fast Brain.

Patient-contacting-materials comparison information		
Feature	Medrad 1.5 Tesla 8-Receiver Neurovascular Coil	1.5 Tesla 16-Channel Receive-only Head Coil
Housing materials	Polyurethane; Fire rated UL 94V-0	Polycarbonate; Fire rated UL 94V-0
Comfort pad	Cotton material embedded with urethane and fire rated to CAL 117.	Cotton material embedded with urethane and fire rated to CAL 117.

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

Mr. Fahad Alradady
President and CEO
MR Medical Solutions LLC
310 Vista Park Drive
PITTSBURG PA 15205

AUG 31 2010

Re: K093689
Trade/Device Name: 1.5 Tesla 16-Channel Receive-only Phased-array Head Coil for Siemens
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: August 12, 2010
Received: August 12, 2010

Dear Mr. Alradady:

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

Indications for Use

510(k) Number (if known): K093689

Device Name: 1.5 Tesla 16-Channel Receive-only Phased-array Head Coil for Siemens

Indications for Use:

The MR Medical Solutions 1.5 Tesla 16-Channel Receive-only Phased-array Head Coil is a receive-only coil intended to be used with 1.5T Siemens superconducting MRI scanners. The coil is intended to facilitate complete MR imaging of the intracranial/extracranial neurovasculature and skull base.

The MR Medical Solutions 1.5 Tesla 16-Channel Receive-only Phased-array Head Coil is a receive-only coil and is indicated for use only under the supervision of a physician or certified MR technologist who is trained in the field of Diagnostic Magnetic Resonance Imaging.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093689