

K110591

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MAR 29 2011

510(k) Summary
(As required by section 21 CFR 807.92(c))

Contact: MR Instruments, Inc.
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Chief Operating Officer
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Date Prepared: February 7, 2011

Product Trade Name: MC 1504G-16R, 1.5T, 16-Channel Head Coil
MC 3004G-16R, 3.0T, 16-Channel Head Coil

Common/Usual Name: Head Coil / Brain Coil

Classification Name: Magnetic Resonance Diagnostic Device, Class II
(21 CFR 892.1000, Product Code MOS)

Predicate Device: HRH-63-8, 1.5T, 8-Channel Head Array,
MRI Devices (K013159)
HRH-127-8, 3.0T, 8-Channel Head Array,
MRI Devices (K022372)

Manufacturer: MR Instruments, Inc.
5610 Rowland Road, Suite 145
Minnetonka, MN 55343

Establishment Registration: 3003852428

Device Description:

The MC 1504G-16R (1.5T) and MC 3004G-16R (3.0T) Head Coils are multi-channel receive only coils consisting of 16 RF elements. Each RF element has active and passive blocking networks, and integrated preamplifiers. The MC 1504G-16R RF elements are tuned to ¹H at 1.5T (63.9 MHz), while the MC 3004G-16R RF elements are tuned to ¹H at 3.0T (127.8 MHz). The coil housing is constructed out of a rigid plastic with an opening for patient viewing and comfort; the head support/base is included with each coil assembly.

Statement of Intended Use:

This coil is indicated for use in conjunction with a Magnetic Resonance Scanner to produce images and/or spectra of the head, that when interpreted by a trained physician yield information that may assist in diagnosis.

Summary of Technological Characteristics in Comparison to the Predicate Device:

The MC 1504G-16R (1.5T) and MC 3004G-16R (3.0T) Head Coils are substantially equivalent to the MRI Devices HRH-63-8, 1.5T (K013159) and HRH-127-8, 3.0T (K022372) Head Arrays, respectively.

The proposed and predicate devices are both multi-channel RF receive only head coils that utilize phased array technology. Additionally, both the proposed and predicate devices are designed to work in conjunction with a Magnetic Resonance Scanner, and have similar size, shape and construction.

The primary difference between the proposed and predicate devices is that the predicate utilizes an 8 element phased array RF structure as opposed to a 16 element phased array RF structure. The use of additional elements may increase coil sensitivity and reduce data acquisition time.

Summary of Non-Clinical Testing:

Design verification and validation testing was performed to ensure that the coil design specifications and customer requirements were met.

Electrical bench measurements were performed to ensure proper assembly, function and tuning to established specifications.

Electrical/mechanical device safety and system safety (phantoms) testing were conducted in accordance with IEC 60601-1.

Performance evaluations (phantoms) were completed using the proposed and predicate devices with comparative signal-to-noise (SNR) measurements based on NEMA MS-1.

Volunteer scans were performed with the proposed and predicate devices to acquire paired images using routine clinical scan sequences. Scan images were then reviewed in blind fashion by registered technologists in magnetic resonance to demonstrate equivalence in resulting image quality.

All system testing was conducted using 1.5T and 3.0T Magnetic Resonance Scanner systems running standard clinical applications.

Summary of Clinical Testing:

No additional clinical evaluations of the head coil devices for this use have been conducted.

Conclusions:

The MC 1504G-16R (1.5T) and MC 3004G-16R (3.0T) Head Coils are substantially equivalent to the MRI Devices HRH-63-8, 1.5T (K013159) and HRH-127-8, 3.0T (K022372) Head Arrays, respectively.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MR Instruments, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

MAR 29 2011

Re: K110591

Trade/Device Name: MR Instruments, Inc., MC 1504G-16R, 1.5T, 16 Channel Head Coil;
MC 3004G-16R, 3.0T, 16 Channel Head Coil

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: MOS

Dated: March 16, 2011

Received: March 17, 2011

Dear Mr. Job:

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.

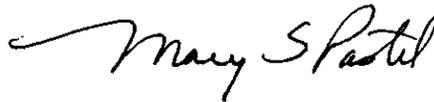
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,

A handwritten signature in black ink that reads "Mary S. Pastel". The signature is fluid and cursive, with a long horizontal stroke at the beginning.

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

Enclosure

K110591

Indications for Use

510(k) Number (if known): _____

Device Name: **MR Instruments, Inc.**
MC 1504G-16R, 1.5T, 16-Channel Head Coil
MC 3004G-16R, 3.0T, 16-Channel Head Coil

Indications for Use:

This coil is indicated for use in conjunction with 1.5T and 3.0T GE Healthcare Magnetic Resonance Scanner systems to produce images and/or spectra of the head, that when interpreted by a trained physician yield information that may assist in diagnosis.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices Evaluation (OIVD)

Mary S. Pasold

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

510(k) K110591