Section 2 - 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. *Contact Person*

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MR Instruments, Inc., Inc.
4802 Park Glen Road
Minneapolis, MN 55416

2. *General Information*

Name: TEM 3000G Head Coil

Trade Name: TEM 3000 Head Coil

Common Name: Head Coil

Classification Name: Magnetic Resonance Diagnostic Device

Classification: This device is classified by the Radiology Panel into Class II, (21 CFR 892.1000)

3. *Device Description*

The TEM 3000G Head Coil is a 15-element, quadrature transmit/receive coil. The coil elements and associated circuitry are enclosed in a rigid housing to prevent any exposure to patient or environment. The coil housing employs a large open viewing window on the top. The coil design facilitates the scanning of patients with different head sizes and maximizes patient comfort and ease of use.

The predicate device, manufactured for General Electric Company, Milwaukee, WI (USA) by GE Medical Systems (India) Private LTD, Split Head Coil Assembly for G3 (K040444), is also quadrature transmit/receive coil. The TEM 3000G's fundamental construction and use of materials (as defined above) is similar to the predicate device. (See Attachment B for device drawings.)

4. *Intended Use*

The MR Instruments TEM 3000G Head Coil is designed to provide Magnetic Resonance Images of the brain, soft tissues and vasculature of the head. The TEM

3000G Head Coil is designed for use with the GE Signa 3.0T Excite MR System manufactured by GE.

5. *Substantial Equivalence Comparison*

The TEM 3000G Head Coil is substantially equivalent to the following device with respect to intended use and design:

- GE Signa 3.0T Excite MR System (Split Head Coil Assembly for G3) (K40444) manufactured for General Electric Company (Milwaukee, WI, USA) by GE Medical Systems (India) Private LTD, Banagalore, India

The similarities between the two devices is that they are both quadrature transmit and receive RF coils designed to work with the GE Signa 3.0T Excite scanner. Both coils are similar in size, shape and construction.

The primary difference between the two devices is that the predicate utilizes birdcage technology as opposed to transverse electromagnetic (TEM) technology, which requires less RF power to achieve high-resolution imaging.

6. *Summary of Studies*

Performance testing was completed to verify the design specifications necessary for the designed for use with the GE Healthcare Signa® 3.0T MR System modification and to support the compatibility of the GE based Head Coil. Test results support the safety and performance of the TEM 3000G Head Coil for its intended use.

7. *Conclusion (statement of equivalence)*

The data and information provided in this submission supports a substantial equivalence determination, and, therefore, 510(k) premarket notification clearance of the TEM 3000G Head Coil.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2005

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

Re: K052200
Trade/Device Name: TEM 3000G Head Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: August 10, 2005
Received: August 12, 2005

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K052200

MR INSTRUMENTS INC

Indications for Use Statement

The MR Instruments TEM 3000G Head Coil is designed to provide Magnetic Resonance Images of the brain, soft tissues and vasculature of the head. The TEM 3000G Head Coil is designed for use with the GE Signa 3.0T Excite MR System manufactured by GE.

Prescription Use ✓

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number ~~July 29, 2005~~ K052200