K080820

MR INSTRUMENTS INC

Section 2 - 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

APR - 2 2008

1. *Contact Person*

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2. *General Information*

Name:	TEM 3002G-HN Dual Tune headcoil
Trade Name:	TEM 3002G-HN Dual Tune headcoil
Common Name:	Headcoil
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 3002G-HN Dual Tune headcoil is a quadrature transmit/receive RF coil tuned to proton (^{1}H) and sodium (^{23}Na) frequencies 3T. The TEM resonant elements and associated matching and quadrature splitting circuitry are enclosed in a rigid plastic housing to prevent any exposure to patient or environment.

The predicate devices are also quadrature transmit/receive RF headcoils. All have similar construction, size and shape. All are tuned to proton (^{1}H) resonant frequency at 3T and two are dual resonant, one at phosphorus (^{31}P) and one at carbon (^{13}C).

4. *Intended Use*

The MR Instruments TEM 3002G-HN Dual Tune headcoil is to be used in conjunction with a 3T Magnetic Resonance Imaging system to produce proton (^{1}H) images and spectra of the internal structures of the head. In addition, sodium (^{23}Na) images and spectra may be obtained during the same exam without changing the coil. These images and/or spectral information of the head, when interpreted by a trained physician, may yield information that may assist in diagnosis.

5. *Substantial Equivalence Comparison*

The TEM 3002G-HN Dual Tune headcoil is substantially equivalent to the following devices with respect to safety, intended use and design:

Coil Name	Premarket Notification	Clearance Date
GE Healthcare Split Head Coil Assembly for G3, for use with a Signa 3T MR system for producing proton (^{1}H) MR images and spectra	K040444	April 14, 2004
Siemens Medical Solutions ^{31}P/^{1}H headcoil for MAGNETOM Allegra MR system for producing phosphorus (^{31}P) and proton (^{1}H) MR images and spectra	K042617	November 5, 2004
Siemens Medical Solutions ^{13}C/^{1}H headcoil for MAGNETOM Allegra MR system for producing carbon (^{13}C) and proton (^{1}H) MR images and spectra	K042718	November 12, 2004

Similarities between the devices are devices in that they are all transmit and receive RF coils designed to work in conjunction with 3T MR System for acquiring proton (^{1}H) diagnostic images and spectra of the internal structures of the head. The double resonance coils are similar in frequency as noted below. In addition, all coils are similar in size, shape and construction.

Note: The resonance frequency of ^{13}C = 32.4 MHz, ^{23}Na = 33.8 MHz, and ^{31}P = 5^{1}.6 MHz at 3T.

The primary differences between the devices are that the TEM 3002G-HN coil adds sodium (^{23}Na) imaging capability instead of phosphorus (^{31}P) or carbon (^{13}C). The GE Healthcare Split Top Coil is not a double resonant coil and requires switching coils to obtain images or spectra at other frequencies.

6. *Summary of Studies*

Verification and validation testing was performed to ensure that the coil design requirements specification and customer requirements specification were met. Testing activities included electrical bench measurements, electrical/mechanical safety tests, MR system safety and performance tests with phantoms and volunteer scans. MR system tests were conducted using the GE Healthcare Signa 3T MR system running standard clinical applications.

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 3002G-HN Dual Tune headcoil.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

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

APR - 2 2008

Re: K080820
Trade/Device Name: TEM 3002G-HN Dual Tune headcoil
Regulation Number: 21 CFR 872.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: March 22, 2008
Received: March 24, 2008

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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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

Indications for Use Statement

The MR Instruments TEM 3002G-HN Dual Tune headcoil is to be used in conjunction with a 3T Magnetic Resonance Imaging system to produce proton (^{1}H) images and spectra of the internal structures of the head. In addition, sodium (^{23}Na) images and spectra may be obtained during the same exam without changing the coil. These images and/or spectral information of the head, when interpreted by a trained physician, may yield information that may assist in diagnosis.

This device is for prescription use.

(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 K080820