K040937

APR 2 3 2004

MR INSTRUMENTS INC

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	MR Instruments, Inc.
2.	*Address:*	4802 Park Glen Road Minneapolis, MN 55416
3.	*Telephone:*	952.746.1435
4.	*Contact Person:*	Gene Berghoff
5.	*Date Prepared:*	April 7, 2004
6.	*Registration Number:*	Pending

B. Device

1.	*Name:*	TEM 3000 Head Coil
2.	*Trade Name:*	TEM 3000 Head Coil
3.	*Common Name:*	Head Coil
4.	*Classification Name:*	Magnetic Resonance Diagnostic Device
5.	*Product Code:*	90MOS
6.	*Class:*	II
7.	*Regulation Number:*	892.1000

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II

K040937

MR INSTRUMENTS INC

C. Identification of Legally Marketed Devices

1. *Name:* Magnetom Trio Head Coil
2. *K Number:* K021330
3. *Date Cleared:* July 25, 2002

D. Description of the Device

The TEM 3000 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. Included with the coil housing is a Head Support/Coil Base. It allows the coil to be slid back for better patient access.

E. Intended Use Statement

The MR Instruments TEM 3000 Head Coil is intended for ^{1}H high-resolution whole-head adult and pediatric imaging. Typical applications include functional MRI, spectroscopy and angiography. It is compatible with the Siemens 3T Magnetom Trio MR System (K021330).

F. Technological Characteristics Summary

The TEM 3000 Head coil is similar to the predicate device, the USA Instruments 3T head coil manufactured for the Siemens Magnetom Trio system, in regard to its construction and operation. The key difference is the use of TEM (Transverse Electromagnetic) technology rather than the commonly used "Birdcage" technology. This means the coil develops the necessary RF field using "distributed" (transmission line) elements rather than "lumped" or discrete components. As a result, the TEM coil has the potential of being more efficient at higher frequencies.

4802 Park Glen Road Minneapolis, MN 55416 952-746-1435 fax: 952-746-1437

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2004

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

Re: K040937
Trade/Device Name: TEM 3000 Head Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: April 8, 2004
Received: April 12, 2004

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 (PMA), 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

Indication for Use Form

510(k) Number: K040937

Device Name: TEM 3000 Head Coil

Indications for Use: The TEM 3000 head coil is designed to provide Magnetic Resonance Images of the brain, soft tissues and vasculature of the head. The TEM 3000 head coil is designed for use with the Magnetom Trio 3.0 Tesla scanner manufactured by Siemens Medical Systems.

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR OVER-THE-COUNTER USE ____
(optional Form 1-2-96)

David A. Seltzman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040937