K060758

510(k) Summary

OR Head Coil 1.5T

MAY - 5 2006

Date of Summary Preparation: March 15, 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

1. General Information

Importer/Distributor
Name and Address
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Establishment Registration Number
2240869

Manufacturing Site
Name and Address
Noras Röntgen- und Medizintechnik GmbH
Leibnizstrasse 4
97204 Höchberg
Germany

Establishment Registration Number
Establishment Registration 3004929307

Owner/Operator 9071737

2. Contact Person

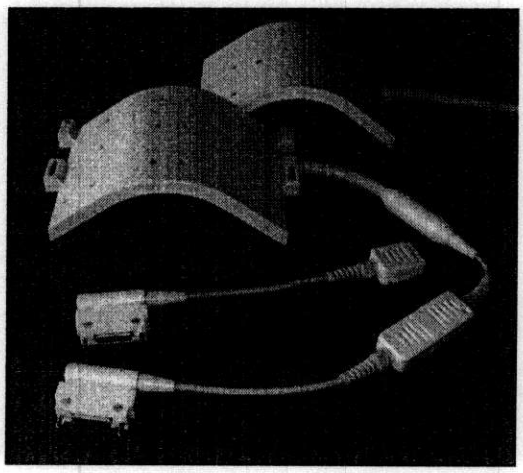
Judy Campbell
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Telephone: (610) 448-4918
Fax: (610) 448-1787
Email Address: judith.campbell@siemens.com

3. Device Name and Classification

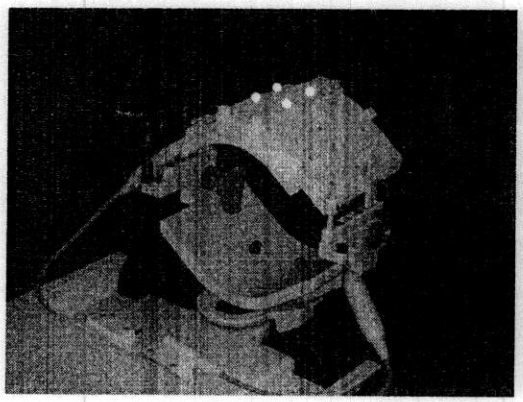
Trade Name:	**OR Head Coil 1.5T**
Common Name:	**OR Head Coil 1.5T**
Classification Name:	Magnetic Resonance Diagnostic Device
Classification Panel:	Radiology
CFR Number:	21 CFR § 892.1000
Device Class:	II
Product Code:	90MOS

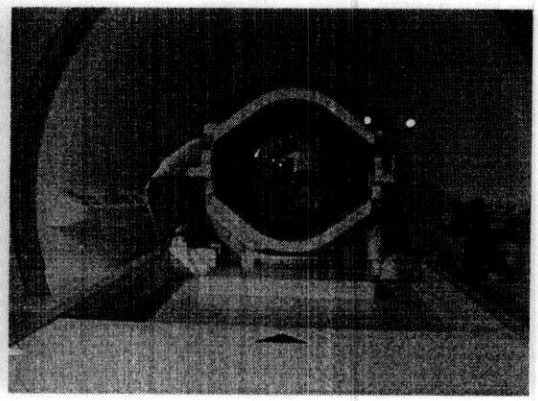
4. Device Description

The OR Head Coil 1.5T is an 8-channel phased array coil. The coil is divided into a bottom and a top array of 4 channels each. Each channel is tuned to the Larmor frequency of the 1H spin in a magnetic field of 1.5T, 63.6 MHz. Each coil is connected to the MAGNETOM system by a separate cable.



Use of the OR Head Coil 1.5T requires the Siemens OR Head Holder. The pictures below show the complete set.





5. Intended Use

The intended use of the Noras OR Head Coil 1.5T is the MR examination of the human brain just before, during and at the end of the brain surgery in the operating room. It can also be used as a standard diagnostic head coil for diagnostic examinations and fMRI.

6. Substantial Equivalence

Noras and Siemens believe that, within the meaning of the Safe Medical Devices Act of 1990, the 8-channel phased array OR head coil 1.5T for the Magnetom Systems is substantially equivalent to the following coil:

Coil Name	Pemarket Notification	Clearance Date
MRI Devices Corporation (Now Known as Invivo Corporation) High Resolution Head Coil -Model HRH-63-8	K013159	October 16, 2001

7. Summary of Technological Characteristics of the Principal Device as Compared with the predicate Device

Although the MRI Devices High Resolution Head Coil is limited for use outside the operating room, we believe that both coils are substantially equivalent.

8. General Safety and Effectiveness Concerns

The OR Head Coil 1.5T will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the IEC standards for safety issues with the Magnetic Resonance Imaging Devices, IEC 60601-2-33: 2002. This will assure that the performance of this device can be considered safe and effective when used with the currently available MAGNETOM 1.5T systems.

The NEMA Tests can be found in Appendix C. The NEMA Tests were done on Software platform syngo MR2004A. We have included the Common Risk Analysis for syngo MR2006A, which is the same functionality as syngo platform MR 2004A. We believe the NEMA tests on the Symphony are applicable to all MAGNETOM 1.5T systems.

9. Conclusion as to Substantial Equivalence

Noras and Siemens believe that, within the definition of the Safe Medical Devices Act of 1990, the Noras 8-channel phased array OR head coil 1.5T is substantially equivalent to the predicate device listed above.

Hubert Noras
President

March 16, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY - 5 2006

Ms. Judith Campbell
Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway, E-50
MALVERN PA 19355

Re: K060758
Trade/Device Name: Noras OR Head Coil 1.5 T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: March 16, 2006
Received: March 21, 2006

Dear Ms. Campbell:

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

510(k) Number (if known): K060758

Device Name:

Noras OR Head Coil 1.5 T

Indications for Use:

The intended use of the Noras OR head coil 1.5 T is, in conjunction with a Magnetic Resonance Scanner, the MR examination of the human brain just before, during and at the end of the brain surgery in the operating room. The coil can also be used as a standard diagnostic head coil for diagnostic examinations and fMRI (Functional Magnetic Resonance Imaging).

Used in the 1.5T MAGNETOM Systems, it is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head.

When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060258

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