K033235

DEC 17 2003

SUMMARY OF SAFETY AND EFFECTIVENESS

1. Device Name:	Magnetic Resonance Imaging Accessory
2. Proprietary Name:	Gemini III Hybrid Tx/Rx 4 Channel Head Coil
3. Classification:	Class II
4. Establishment Registration #:	1529041
5. Manufacture Facility Location:	USA Instruments, Inc. 1515 Danner Drive Aurora, Ohio 44202, USA Telephone: 330-562-1000; Fax: 330-562-1422.
6. Performance Standard:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use:	The Gemini III Hybrid Tx/Rx 4 Channel Head Coil consists of a transmit birdcage coil and a receive only 4 channel phased array RF coil, used for obtaining diagnostic images of the brain, cervical spine, soft tissue of the neck and upper chest in Magnetic Resonance Imaging Systems. The Gemini III Hybrid Tx/Rx 4 Channel Head Coil is compatible with SENSE technology and designed for use with the Allegra 3.0T MRI systems manufactured by Siemens Medical Solutions.
8. Device Description:	The Gemini III Hybrid Tx/Rx 4 Channel Head Coil consists of a transmit birdcage coil and a receive only 4 channel phased array RF coil. The coil has a rigid enclosure. The open, patient friendly design eases patient handling and positioning and maximizes patient comfort. The coil elements and accessory electronics are enclosed in a rigid plastic housing, which is fire rated and has a high impact and tensile strength.

9. Safety and Effectiveness

Gemini III Hybrid Tx/Rx 4 Channel Head Coil product features	**Comparison to predicate device or other 510(k) cleared products**
Intended Use: Imaging of the brain, cervical spine, soft tissue of the head and neck,	-Similar to the Magnetom Trio 3.0T Head Coil manufactured by USA Instruments, Inc. (K021262)
Indications for Use: Identical to routine MRI imaging	-Similar to the Magnetom Trio 3.0T Head Coil manufactured by USA Instruments, Inc. (K021262)
Coil Enclosure Material: Flame Retardant Polyurethane	-Similar to the Magnetom Trio 3.0T Head Coil manufactured by USA Instruments, Inc. (K021262)
Coil Design: The coil design consists of a transmit birdcage coil and a receive only phased array coil.	-Similar to the Magnetom Trio 3.0T Head Coil manufactured by USA Instruments, Inc. (K021262)
Decoupling: active and passive switching diodes	-Similar to the Magnetom Trio 3.0T Head Coil manufactured by USA Instruments, Inc. (K021262)
Prevention of RF Burns: The coil uses pin diodes to isolate the receive elements from the transmit coil; coil elements and circuitry are enclosed in a non-conductive housing	-Similar to the Magnetom Trio 3.0T Head Coil manufactured by USA Instruments, Inc. (K021262)
Radio Frequency Absorption: Power deposition during imaging is limited by SAR algorithm	-Similar to the Magnetom Trio 3.0T Head Coil manufactured by USA Instruments, Inc. (K021262)
Formation of Resonant Loop: Active diodes isolate the coil elements from RF fields; length of cable and stiffness does not permit looping	-Similar to the Magnetom Trio 3.0T Head Coil manufactured by USA Instruments, Inc. (K021262)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2003

Ms. Christie Shumaker
Manager, QA and Regulatory
USA Instruments, Inc.
1515 Danner Drive
AURORA OH 44202

Re: K033235
Trade/Device Name: Gemini III Hybrid Tx/Rx
4 Channel Head Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance
diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: September 29, 2003
Received: October 6, 2003

Dear Ms. Shumaker:

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

510(k) Number (if known): K033235

Device Name: Gemini III Hybrid Tx/Rx 4 Channel Head Coil

Indications for Use: The Gemini III Hybrid Tx/Rx 4 Channel Head Coil is designed to provide Magnetic Resonance Images of the brain, upper cervical spine, and the soft tissues and vasculature of the head and neck. The Gemini III Hybrid Tx/Rx 4 Channel Head Coil is designed for use with the Siemens Allegra 3.0T scanner manufactured by Siemens Medical Solutions, Inc.

Anatomic Regions: brain, upper cervical spine, and the soft tissues and vasculature of the head and neck
Nuclei Excited: Hydrogen

The indications for use are the same as for standard imaging:

The 3.0T MRI system is indicated for use as an NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR signal, (2) depend upon NMR parameters (proton density, spin lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

(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 _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033235