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SUMMARY OF SAFETY AND EFFECTIVENESS

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1. Device Name :	Magnetic Resonance Imaging Accessory
2. Proprietary Name :	Premier III Phased Array CTL Spine 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 Premier III Phased Array CTL Spine Coil is a receive-only phased array RF coil, used for obtaining diagnostic images of the spine region (cervical, thoracic and lumbar anatomy) in Magnetic Resonance Imaging Systems. The indications for use are the same as for standard MR Imaging. The Premier III Phased Array CTL Spine Coil is designed for use with the GE Medical Systems 3.0Tesla MRI scanner.
8. Device Description:	The Premier III Phased Array CTL Spine Coil is a multi-element phased array receive-only coil. The coil is shaped to conform to the contours of the spine and has been designed to maximize comfort and ease of use. The elements and associated circuitry are enclosed in a housing made of plastic materials, which are fire rated and have high impact and tensile strength.

9. Safety and Effectiveness

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Premier III Phased Array CTL Spine Coil Product Features	Comparison to predicate device or other 510(k) cleared product
Intended Use: Imaging of the spine.	-Similar to the Premier 7000 C/T/L Spine Coil manufacture by USA Instruments, Inc. (K980157) -Similar to the Magna 5000 CTL Spine Coil manufactured by USA Instruments, Inc. (K994345)
Indications for Use: Identical to routine MRI imaging	-Similar to the Premier 7000 C/T/L Spine Coil manufacture by USA Instruments, Inc. (K980157) -Similar to the Magna 5000 CTL Spine Coil manufactured by USA Instruments, Inc. (K994345)
Coil Material: ABS Plastic Polycarbonate Plastic	-Similar to the Premier 7000 C/T/L Spine Coil manufacture by USA Instruments, Inc. (K980157) -Similar to the Magna 5000 CTL Spine Coil manufactured by USA Instruments, Inc. (K994345)
Coil Design: Receive-only phased array design	-Similar to the Premier 7000 C/T/L Spine Coil manufacture by USA Instruments, Inc. (K980157) -Similar to the Magna 5000 CTL Spine Coil manufactured by USA Instruments, Inc. (K994345)
Decoupling: RF Chokes with Switching Diodes	-Similar to the Premier 7000 C/T/L Spine Coil manufacture by USA Instruments, Inc. (K980157) -Similar to the Magna 5000 CTL Spine Coil manufactured by USA Instruments, Inc. (K994345)
Prevention of RF Burns: Does not transmit RF Power, Decoupling isolates the coil elements from RF fields during RF transmission, Coil elements and circuitry are enclosed in a non-conductive housing.	-Similar to the Premier 7000 C/T/L Spine Coil manufacture by USA Instruments, Inc. (K980157) -Similar to the Magna 5000 CTL Spine Coil manufactured by USA Instruments, Inc. (K994345)
Radio Frequency Absorption: Coil is a receive only coil and does not transmit RF power	-Similar to the Premier 7000 C/T/L Spine Coil manufacture by USA Instruments, Inc. (K980157) -Similar to the Magna 5000 CTL Spine Coil manufactured by USA Instruments, Inc. (K994345)
Formation of Resonant Loops: Decoupling isolates coil elements from RF fields during RF transmission. Length of cable and stiffness does not permit looping	-Similar to the Premier 7000 C/T/L Spine Coil manufacture by USA Instruments, Inc. (K980157) -Similar to the Magna 5000 CTL Spine Coil manufactured by USA Instruments, Inc. (K994345)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratio
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2002

Mr. Rony Thomas
Vice President, Marketing
and Programs
USA Instruments, Inc.
1515 Danner Drive
AURORA OH 44202

Re: K013595
Trade/Device Name: Premier III Phased Array
CTL Spine Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: October 26, 2001
Received: October 30, 2001

Dear Mr. Thomas:

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 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.

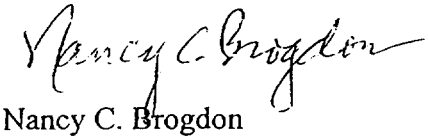
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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:

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" (21 CFR Part 807.97). 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013595

Device Name: Premier III Phased Array CTL Spine Coil

Indications for Use: The Premier III Phased Array CTL Spine Coil is designed to provide Magnetic Resonance Images of the spine anatomy. The Premier III Phased Array CTL Spine Coil is designed for use with the GE Medical Systems 3.0Tesla scanner.

Anatomic Regions: Spine
Nuclei Excited: Hydrogen

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

The GE Medical Systems 3.0Tesla 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 ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013595