JUN 20 1997

SUMMARY OF SAFETY AND EFFECTIVENESS K971246

1. Device Name :	Magnetic Resonance Imaging Accessory
2. Proprietary Name :	Leo 7000 Quadrature Knee Coil
3. Classification :	Class II
4. Establishment Registration #:	1529041
5. Manufacture Facility Location:	USA Instruments, Inc., 675-B Alpha Drive, Highland Heights, Ohio 44143, USA Telephone: 216-442-5920; Fax: 216-442-5919.
6. Performance Standard:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use:	The Leo 7000 Quadrature Knee Coil is a receive-only quadrature RF coil, used for obtaining diagnostic images of the knee anatomy in Magnetic Resonance Imaging systems. The indications for use are the same as for standard MR Imaging. The Quadrature Knee Coil is designed for use with GE Signa (1.5 Tesla) MRI scanner manufactured by GE Medical Systems.
8. Device Description:	The Leo 7000 Quadrature Knee Coil is a bird-cage resonator. The electrical circuitry is enclosed in a durable housing assembly made of polyurethane material, which is fire rated and has high impact and tensile strength. The Leo 7000 Quadrature Knee Coil is a quadrature volume coil with a split-top design.

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9. Safety and Effectiveness

Parameter	LEO 7000 Quadrature Knee Coil	Same as Predicate Device
Intended Use	Knee Imaging Applications	MR Quadrature Knee Coils Hitachi Medical Systems (K914263) Lower Extremity Coil, OUTLOOK MRI System Picker International, Inc. (K945827)
Indications for Use	Identical to routine MRI imaging	Lower Extremity Coil, OUTLOOK MRI System Picker International, Inc. (K945827) Profile 7000 C-Spine Coils, US ASIA Instruments, Inc. (K943440)
Coil Body Former Material	Flame retardant Polyurethane	Lower Extremity Coil, Head Coil, and Vascular Head and Neck Coil, OUTLOOK MRI System Picker International, Inc. (K945827)
Coil Design	Quadrature receive-only, bird-cage resonator	Quadrature head coil and Quadrature MRA coil, HI-STAR MRI system, Health Images, Inc. (K944724)
Decoupling	RF Chokes with Switching Diodes	Lower Extremity Coil, OUTLOOK MRI System Picker International, Inc. (K945827) Flexible Phased Array Spine Coil, Picker International, Inc. (K960497).
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.	Profile 7000 C-Spine Coils US ASIA Instruments, Inc. (K943440). Lower Extremity Coil, OUTLOOK MRI System Picker International, Inc. (K945827)
Radio Frequency Absorption	Coil is a receive only coil and does not transmit RF power	Profile 7000 C-Spine Coils, US ASIA Instruments, Inc. (K943440)
Formation of Resonant Loops	Decoupling isolates coil elements from RF fields during RF transmission. Length of cable and stiffness do not permit looping.	Profile 7000 C-Spine Coils, US ASIA Instruments, Inc. (K943440) Flexible Phased Array Spine Coil Picker International, Inc. (K960497).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

Rony Thomas
Manager, Regulatory Affairs
USA Instruments, Inc.
675-B Alpha Drive
Highland Heights, Ohio 44143

Re: K971246
Leo 7000 Quadrature Knee Coil
Dated: April 2, 1997
Received: April 3, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Mr. Thomas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971246

Device Name: Leo 7000 Quadrature Knee Coil

Indications for Use: The Leo 7000 Quadrature Knee Coil is designed to provide Magnetic Resonance Images of the knee anatomy. The Leo 7000 Quadrature Knee Coil is designed for use with the GE Signa (1.5 Tesla) MRI Scanner.

Anatomic Regions: Knee Joint
Nuclei Excited: Hydrogen

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

The GE Signa 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971246

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)