

SUMMARY OF SAFETY AND EFFECTIVENESS

K972205

1. Device Name : Magnetic Resonance Imaging Accessory
2. Proprietary Name : Alpha 7000 Quadrature Wrist Coil SEP - 5 1997
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 Alpha 7000 Quadrature Wrist Coil is a receive-only quadrature RF coil, used for obtaining diagnostic images of the wrist and hand anatomy in Magnetic Resonance Imaging systems. The indications for use are the same as for standard MR Imaging. The Quadrature Wrist Coil is designed for use with GE Signa (1.5 Tesla) MRI scanner manufactured by GE Medical Systems.
8. Device Description: The Alpha 7000 Quadrature Wrist Coil consists of two volume RF coil elements in a quadrature design. The elements and the associated circuitry are enclosed in a durable housing made of polyurethane material, which is fire rated and has high impact and tensile strength.

please turn over

9. Safety and Effectiveness

<b>Parameter</b>	<b>Features of Alpha7000 Quadrature Wrist Coil</b>	<b>Same as Predicate Device</b>
Intended Use	Wrist and Hand Imaging Applications	Quadrature Wrist and Hand Coil MRI Devices Corp. (K931008)
Indications for Use	Identical to routine MRI imaging	Quadrature Wrist and Hand Coil MRI Devices Corp. (K931008)  Profile 7000 Quadrature Volume Neck Coil USA Instruments, Inc. (K964531)
Coil Body 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 design	Profile 7000 Quadrature Volume Neck Coil USA Instruments, Inc. (K964531)
Decoupling	RF Chokes with Switching Diodes	Profile 7000 Quadrature Volume Neck Coil USA Instruments, Inc. (K964531)
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 Quadrature Volume Neck Coil USA Instruments, Inc. (K964531)
Radio Frequency Absorption	Coil is a receive only coil and does not transmit RF power	Profile 7000 Quadrature Volume Neck Coil USA Instruments, Inc. (K964531)
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 Quadrature Volume Neck Coil USA Instruments, Inc. (K964531)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP - 5 1997

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

Re: K972205  
Maximum 7000 Quadrature Extremity Coil  
Dated: May 6, 1997  
Received: June 12, 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 Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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/dsmmain.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): \_\_\_\_\_

Device Name: Alpha 7000 Quadrature Wrist Coil

**Indications for Use:** The Alpha 7000 Quadrature Wrist Coil is designed to provide Magnetic Resonance Images of the wrist and hand anatomy. The Alpha 7000 Quadrature Wrist Coil is designed for use with the GE Signa (1.5 Tesla) MRI Scanner.

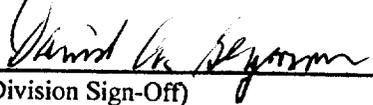
Anatomic Regions: Wrist and hand anatomy  
Nuclei Excited: Hydrogen

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 K972205

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)