K982339

SEP - 4 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

1. Device Name :	Magnetic Resonance Imaging Accessory
2. Proprietary Name :	Flow 7000 Peripheral Vascular 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 Flow 7000 Peripheral Vascular Coil is a receive-only quadrature-phased array RF coil, used for obtaining diagnostic images of the vasculature and soft tissue anatomy, extending from the abdomen to the foot region in Magnetic Resonance Imaging Systems. The indications for use are the same as for standard MR Imaging. The Flow 7000 Peripheral Vascular Coil is designed for use with the 1.5T Signa MRI scanner manufactured by GE Medical Systems.
8. Device Description:	The Flow 7000 Peripheral Vascular Coil is a 12 element quadrature, phased array, receive-only coil. The coil consists of two sections: an upper and lower section, which are positioned above and below the patient's body (lower torso and legs). The coil sections which contain the coil elements and accessory coil electronics, is enclosed to prevent any exposure to the patient or environment.

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9. Safety and Effectiveness

Parameter	Flow 7000 Phased Array Peripheral Vascular Coil	Same as Predicate Device
Intended Use	Imaging of vasculature and tissue extending from the torso to the feet.	Peripheral Vascular Coil, Medical Advances Inc. (K964813)
Indications for Use	Identical to routine MRI imaging	Peripheral Vascular Coil, Medical Advances Inc. (K964813) Profile 7000 Volume Neck Coil, USA Instruments (K964531)
Coil Material	Flame Retardant ABS/PVC Plastic alloy, Flame retardant Polyurethane Plastic Flame retardant Vinyl fabric	Profile 7000 Volume Neck Coil, USA Instruments (K964531) Leo 7000 Quadrature Knee Coil, USA Instruments (K971246) General Purpose Flex Coil, Picker International (K944469)
Coil Design	Receive-only phased array design	Insight 7000 Phased Array Torso Coil, USA Instruments (K972340) Phased Array C/T/L Spine Coil, USA Instruments (K980157)
Decoupling	RF Chokes with Switching Diodes	Insight 7000 Phased Array Torso Coil, USA Instruments (K972340)
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.	Insight 7000 Phased Array Torso Coil, USA Instruments (K972340)
Radio Frequency Absorption	Coil is a receive only coil and does not transmit RF power	Insight 7000 Phased Array Torso Coil, USA Instruments (K972340)
Formation of Resonant Loops	Decoupling isolates coil elements from RF fields during RF transmission. Length of cable and stiffness does not permit looping	Insight 7000 Phased Array Torso Coil, USA Instruments (K972340)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Rony Thomas
Manager, Regulatory Affairs
USA Instruments, Inc.
1515 Danner Drive
Aurora, Ohio 44202

Re: K982339
Flow 7000 Peripheral Vascular Coil
Dated: June 22, 1998
Received: July 6, 1998
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 requirements, 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/dsma/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): K982339

Device Name: Flow 7000 Phased Array Peripheral Vascular Coil

Indications for Use: The Flow 7000 Phased Array Peripheral Vascular Coil is designed to provide Magnetic Resonance Images of the abdominal aorta,peripheral vasculature and soft tissue anatomy. The Premier 7000 Phased Array Spine Coil is designed for use with the GE MR's Signa 1.5T scanner.

Anatomic Regions: Abdominal Vasculature, Peripheral Vasculature and soft tissue
Nuclei Excited: Hydrogen

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

The Signa 1.5T 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 K982339

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