

K972340

SUMMARY OF SAFETY AND EFFECTIVENESS

AUG 21 1997

1. Device Name : Magnetic Resonance Imaging Accessory
2. Proprietary Name : Insight 7000 Phased Array Torso 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 Insight 7000 Phased Array Torso Coil is a receive-only phased array RF coil, used for obtaining diagnostic images of the torso region (chest, abdomen and hips anatomy) in Magnetic Resonance Imaging Systems. The indications for use are the same as for standard MR Imaging. The Insight 7000 Phased Array Torso Coil is designed for use with the Esteem 1.5T MRI scanner manufactured by Elscint MR.
8. Device Description: The Insight 7000 Phased Array Torso Coil is a four loop receive-only coil. The coil consists of two sections: an upper and lower section, which are positioned above and below the patient torso respectively. The bottom section, which contains two loop coils and the accessory coil electronics, is enclosed in a vacuum formed housing which is covered with a foam pad. The housing and foam pad is entirely covered by a cover made of Naughahyde and Cordura Plus® (fabric material). The upper section, which contains two upper loop coils, is covered by a jacket made of identical materials as the bottom section.

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9. Safety and Effectiveness

Parameter	Insight 7000 Phased Array Torso Coil	Same as Predicate Device
Intended Use	Torso Imaging including abdomen, chest, hips	Phased Array Body Coil, Esteem 1.5T MRI System Elscint MR (K962677)
Indications for Use	Identical to routine MRI imaging	Phased Array Body Coil, Esteem 1.5T MRI System Elscint MR (K962677)
Coil Material	ABS Plastic, Naughahyde and Cordura Plus (fabric material)	Phased Array Body Coil, Esteem 1.5T MRI System Elscint MR (K962677) General Purpose Flex Coil Picker International (K944469)
Coil Design	Four coil receive-only phased array design	Phased Array Body Coil, Esteem 1.5T MRI System Elscint MR (K962677)
Decoupling	RF Chokes with Switching Diodes	Phased Array Body Coil, Esteem 1.5T MRI System Elscint MR (K962677)
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.	Phased Array Body Coil, Esteem 1.5T MRI System Elscint MR (K962677)
Radio Frequency Absorption	Coil is a receive only coil and does not transmit RF power	Phased Array Body Coil, Esteem 1.5T MRI System Elscint MR (K962677)
Formation of Resonant Loops	Decoupling isolates coil elements from RF fields during RF transmission. Length of cable and stiffness does not allow permit looping	Phased Array Body Coil, Esteem 1.5T MRI System Elscint MR (K962677) Flexible Phased Array Spine Coil Picker International (K960497)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 1997

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

Re: K972340
Insight 7000 Phased Array Torso Coil
Dated: May 6, 1997
Received: June 24, 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/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): K972340

Device Name: Insight 7000 Phased Array Torso Coil

Indications for Use: The Insight 7000 Phased Array Torso Coil is designed to provide Magnetic Resonance Images of the torso region. The Insight 7000 Phased Array Torso Coil is designed for use with the Elscint MR's Esteem 1.5T scanner.

Anatomic Regions: Torso
Nuclei Excited: Hydrogen

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

The Esteem 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)

Harold G. Beynon
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K972340

Prescription Use _____
(Per 21 CFR 801.109)

OR

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