K050728-31

JUN 28 2005

SUMMARY OF SAFETY AND EFFECTIVENESS
For Modified Device

1. Device Name:	Magnetic Resonance Image Accessory
2. Proprietary Name:	Open Breast Coil with Biopsy Plates
3. Classification:	Class II
4. Establishment Registration #:	1529041
5. Manufacture Facility Location:	USA Instruments, Inc., 1515 Danner Drive, Aurora, Ohio 44202, USA Telephone: 330-995-8572; 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 Open Breast Coil with Biopsy Plates is a phased array, receive-only MRI coil, used for obtaining MR images of the breast and auxiliary tissue. The biopsy plate allows access to the breast anatomy during biopsy procedures. No biopsy needles are included with, or packaged with the Open Breast Coil with Biopsy Plates. The indications for use are the same as for standard MR Imaging. The Open Breast Coil with Biopsy Plates is designed for use with the 0.3T Airis-Elite MRI scanner manufactured by Hitachi Medical System.
8. Device Description:	The Open Breast Coil with Biopsy Plates is a phased array, receive-only MRI coil. The coil consists of three sections: a supporting base and two insulating coil chambers, one for each breast. Each of the hollow coil chambers houses two coil elements that are insulated from the patient by a ridged plastic housing. The coil housing is made of plastic materials, which are fire rated and have high impact and tensile strength. The Open Breast coil with Biopsy plates is designed to offer optimized imaging capabilities and maximum lateral access to each breast for biopsy procedures.

9. Safety and Effectiveness

Modified Device Features	Comparison to Baseline Device
Intended Use: Breast imaging for diagnostic purposes. The coil has a biopsy plate that allows access to the breast.	-Similar to Liberty 5000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K022007)
Indications for Use: Identical to routine MRI imaging.	-Similar to Liberty 5000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K022007)
Coil Enclosure Material: Polyurethane Plastic, ABS Plastic, Polycarbonate and Delrin.	-Similar to Liberty 5000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K022007)
Coil Design: Receive-only phased array design.	-Similar to Liberty 5000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K022007)
Decoupling: RF Chock with Switching Diode.	-Similar to Liberty 5000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K022007)
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 Liberty 5000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K022007)
Radio Frequency Absorption: Coil is a receive-only coil and does not transmit RF power: power deposition during imaging is limited by SAR algorithm.	-Similar to Liberty 5000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K022007)
Formation of Resonant Loop: Decoupling isolates coil elements from RF fields during RF transmission; length of cable and stiffness does not permit looping.	-Similar to Liberty 5000 Breast Coil with Disposable Biopsy Plate manufactured by USA Instruments, Inc. (K022007)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 2005

Mr. David S. Brown
Manager, QA/RA
USA Instruments, Inc.
1515 Danner Drive
AURORA OH 44202

Re: K050728
Trade/Device Name: Open Breast Coil with Biopsy Plates
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: June 6, 2005
Received: June 10, 2005

Dear Mr. Brown:

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 (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 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 Section 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:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

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): K050728

Device Name: Open Breast Coil with Biopsy Plates

Indications for Use: The Open Breast Coil with Biopsy Plates is designed to provide Magnetic Resonance Images of the breast anatomy and aid in guidance during biopsy procedures. The Open Breast Coil with Biopsy Plates is designed for use with the Hitachi Airis Elite .3T scanner.

Anatomic Regions: Breast Anatomy
Nuclei Excited: Hydrogen

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

The Airis Elite .3T 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 ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Legorn

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050728