SUMMARY

K023929

1.0 SUBMITTER INFORMATION:

1.1 Submitter: Advanced Imaging Research, Inc.
4700 Lakeside Avenue, Suite 400
Cleveland, Ohio 44114
Phone: 216-426-1461
Fax: 216-426-1180

FEB 2 1 2003

1.2 Contact: Ravi Srinivasan

1.3 Date: November 22, 2002

2.0 DEVICE NAME:

2.1 Classification Panel: Radiology

2.2 Classification Number: 892.1000 Magnetic Resonance Diagnostic Device

2.3 Product nomenclature: System Magnetic Resonance Imaging

2.4 Product Code(s): 90MOS (Magnetic Resonance Specialty coil)

2.5 Trade/Proprietary Name: None

2.6 PREDICATE DEVICE(S): GE Quadrature Head Coils
IGC-Medical Advances Inc. Quadrature Knee/Foot Coils
K934396 approved 11/24/1993
K001312 approved 06/20/2000

3.0 DEVICE DESCRIPTION:

3.1 FUNCTION

Device function is similar to the predicate devices, and in general any RF coil for MRI.

Advanced Imaging Research, Inc. intends to introduce Quadrature, Volume Coils for adult and pediatric MR. Specifically, Improved Adult Head coils, and Neonate Head and Body Volume coils safe for use with MRI compatible incubator systems are enclosed.

Our Improved Adult Head Coils provide enhanced signal-to-noise ratio (SNR), a high degree of RF homogeneity and is "open" to alleviate patient claustrophobia.

Our Neonate Coils are intended to scan pre- and term neonates and are designed for use with MR compatible incubator systems. The Neonate Head coil is intended to scan the newborn brain, whereas the Neonate Body coil is intended to scan the major organs (heart, spine, abdomen, pelvis etc.) in the torso and extremities.

Approvals are sought for the transmit/receive (T/R) configurations for use with 1.5 & 3T GE, 1.5T Siemens and receive only configuration for use with Philips 1.5T MRI. Part numbering is as follows:

Coil Type	Coil Type	Configuration	Part Number
Adult Head	GE 1.5T	T/R	2-1071-001-A
	GE 3T	T/R	2-1091-001-A
Neonate Head	GE 1.5T	T/R	2*-1071-003-A
	Siemens 1.5T	T/R	2*-2071-003-A
	Philips 1.5T	R	2*-3071-003-A
Neonate Body	GE 1.5T	T/R	2*-1071-004-A
	Siemens 1.5T	T/R	2*-2071-004-A
	Philips 1.5T	R	2*-3071-004-A

Note: For incubator compatible RF coils, " * " will be replaced by " LM "

Device characteristics for the Improved Adult Head and Neonate (Head, Body) coils may be found in Attachments 3 and 4.

3.2 PHYSICAL & PERFORMANCE CHARACTERISTICS

MR is a premier diagnostic/prognostic imaging tool, commonly used to extract functional, bio-chemical, physiological, vascular and anatomical information from the human body at or on the onset of disease. The quality of the MR image however depends on the main magnet field strength, SNR of the RF coils, linearity and speed of the gradients and on the relaxation times T1, T2, proton density, blood flow, chemical shift and susceptibility of the tissue under investigation. A major advantage of MR is that all of the above information can be obtained non-invasively without the use of ionizing radiation.

3.3 GENERAL SAFETY & EFFECTIVENESS STATEMENT

Safe and effective use fo the devices is assured by associated labeling. This labeling includes: advertising brochures, Operator's Manuals provided by us and Site Planning Guide, Instructions for Use (comprised of Clinical User's Guide, User Safety Guide, User Training Guide, User Applications Guide and Q/Q & Maintenance Guide) provided by the MRI OEM to the end user.

4.0 DEVICE INTENDED USE

The intended use of the device is in conjunction with the MR systems. RF coils cannot be used alone by themselves. They have to be used with the MR system to obtain diagnostic quality images and spectra of the subject under investigation. The quality of the image will be dependent on several parameters described above.

Our Improved Adult Head Coils are intended for use with all versions of the GE 1.5 and 3T MRI systems. Our Neonate Head & Body Coils are intended for use with all versions of the GE, Siemens and Philips 1.5T MRI scanners and also for use with the MR Compatible Incubator systems.

- Anatomical Region: Adult Head, Extremity
  Neonate Head, Neonate Body (torso, heart, spine, pelvis, extremity)
- Nucleus Excited: Proton 1H
- Diagnostic Uses: 1D, 2D, 3D T1, T2 Weighting
  Proton Density
  Chemical Shift
  MR Blood Flow
  MR Spectroscopy
- Clinical Use: Images may be interpreted by a trained physician to yield information that can be useful in the determination of a diagnosis.

5.0 DEVICE TECHNOLOGICAL CHARACTERISTICS

Identical to Predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1 2003

Mr. Ravi Srinivasan, M.S.
President
Advanced Imaging Research, Inc.
4700 Lakeside Avenue
CLEVELAND OH 44114

Re: K023929
Trade/Device Name: RF Coils, MRI Adult Head, Neonate Head, and Neonate Body
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: November 22, 2002
Received: November 25, 2002

Dear Mr. Srinivasan:

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 (PMA), it may be subject to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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): K023929

Device Name: RF Coils, MRI, ADULT HEAD, NEONATE HEAD AND NEONATE BODY

Indications for Use:

The RF coils when used in conjunction with the MRI systems *or* RF coils when used with the incubator system and both the incubator and RF coils used in conjunction with the MRI systems provide imaging of the adult head, extremity, neonate head and body. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.

• Anatomical Region:	Adult Head, Extremity Neonate Head, Body (heart, spine, pelvis, extremity)
• Nucleus Excited:	Proton 1H
• Diagnostic Uses:	1D, 2D, 3D T1, T2 Weighting Proton Density Chemical Shift MR Blood Flow MR Spectroscopy

(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, and Radiological Devices
510(k) Number K023929

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801-109)

(Optional Format 1-2-96)