K083541

FEB 24 2009

1.	Manufacturer:	Advanced Imaging Research, Inc. 4700 Lakeside Avenue, Suite 400 (Physical Location) Cleveland, OHIO 44114 PO Box 603220 **(Use for Correspondence)** Cleveland, OHIO 44103 1262 E 49th Street, Suite 400 (Courier Address) Cleveland, OHIO 44114 Phone: 216-426-1461 Fax: 216-426-1180
2.	Registration Number:	3004036149
3.	Contact:	Ravi Srinivasan, President Phone: 216-426-1461 Fax: 216-426-1180 email: ravi@advimg.com
4.	Device Name:	Magnetic Resonance Diagnostic Device
	Proprietary Name:	Neonate Head Coil, Neonate Body Coil
5.	Type of Submission:	Traditional
6.	Classification of Device:	21CFR 892.1000
	Class of Device:	Class II
	Product Code:	90 MOS (Magnetic Resonance Specialty Coil)
7.	Intended Use:	The Neonate (Head, Body) Coil is a quadrature transmit/receive coil used for obtaining diagnostic images and spectra of the (pre- and term) infant head in 1.5 and 3.0 Tesla General Electric, Siemens Medical Solutions and Philips Medical Systems' Magnetic Resonance Imaging (MRI) scanners and magnetic resonance compatible incubator systems. Indications for use are same as that for standard MR imaging.
8.	Device Description:	The Neonate (Head, Body) Coil is a 12 element quadrature,

transmit/receive coil. Coil elements and associated circuitry are enclosed in a rigid former to prevent any exposure to patient or environment. The coil design facilitates scanning of pre-term and term newborn babies with different head and body sizes and maximizes comfort and ease of use.

9. Marketed Device: Neonate Head Coil for GE, Siemens and Philips 3.0T
Neonate Head and Body Coils for Philips 1.5T

10. Comparison to Predicate: 3.0T Philips T/R Head Coil
3.0T Siemens T/R Head and Knee Coils (manufactured by [formerly USA Instruments], GE Medical, Aurora, OH)
1.5T Neonate Body Coil (K023929)

In general, Neonate Coils are similar to Advanced Imaging Research's FDA cleared 1.5T T/R Neonate (Head, Body) Coils in all aspects (K023929), as follows:

Intended use – Proton 1H 1D, 2D, 3D T1, T2 weighting, proton density, chemical shift, diffusion weighted imaging, angiography, functional MRI, chemical shift imaging, spectroscopy

Indications for Use – The Neonate Coils when used in conjunction with the MRI systems *or* Neonate coils when used with the MRI compatible incubator and in conjunction with the MRI systems provide imaging of the infant head and body (torso). When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.

Coil Enclosure Material – Polycarbonate, polyurethane plastic.

Coil Design – 12 element, quadrature transmit/receive design

Transmit/Receive Switching – Fast active pin-diode circuitry

Prevention of RF Burns - Transmit and receive channels are isolated with pin-diodes; coil elements and associated circuitry are enclosed in plastic housing

Radio-Frequency Absorption – Radio-frequency power deposition is limited in the coil specific file embedded in the MRI and by SAR algorithm of the MRI scanner

		Formation of Resonance Loops – Active diodes and RF fuses isolate the coil elements from whole body RF coil transmit; length and routing of output cable does not permit looping
11.	Summary of Studies:	Testing was performed to demonstrate that the 3.0 T Neonate Head Coils meet the predetermined acceptance criteria

Conclusion:

It is the opinion of Advanced Imaging Research that the Neonate (Head, Body) Coils herein are substantially equivalent to Advanced Imaging Research's Neonate (Head, Body) Coils (K023929). Testing and usage of the 3.0T Neonate Coils does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 4 2009

Mr. Ravi Srinivasan, M.S.
President
Advanced Imaging Research, Inc.
4700 Lakeside Avenue, Suite 400
CLEVELAND OH 44114-3834

Re: K083541
Trade/Device Name: Neonate Coils
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 21, 2008
Received: January 15, 2009

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083541

Device Name: Neonate Coils

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Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 K083541