K061281

JUN 19 2006

7 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the PreMarket Notification in accordance with the requirements of 21 CFR Part 807, Subpart E and Section 807.92.

1. Identification of Submitter:

Submitter:	Insight Neuroimaging Systems LLC.
Address:	11 Canterbury St.
	Worcester MA 01610
Phone:	(508) 799-6464
Fax:	(508) 799-6030
Contact:	Patricia A. Milbank
Title:	Regulatory Consultant
Phone:	425-894-9733
Fax	425-822-3648
Date Prepared:	May 5, 2006

2. Identification of Product:

Trade Name:	Insight Head Coil
Regulatory Number:	21 CFR 892.1000
Regulation Name:	Magnetic Resonance Diagnostic Device
Common Name:	Coil, Magnetic Resonance Specialty
Regulatory Class:	Class II
Product Code:	90 MOS
Manufacturer:	Insight Neuroimaging Systems LLC.
	11 Canterbury St.
	Worcester MA 01610

4. Indications for Use

The Insight Head Coil is a quadrature transmitting and receiving device used to produce magnetic resonance images of the head regions that can be interpreted by a trained radiologist. This device provides a closed, ergonomic package with many patient friendly features including a shorter coil length so that no part of the coil will be over the patient's eyes, nose or mouth.

5. Device Description:

The Insight Head Coil is a quadrature transmitting and receiving device for use in magnetic resonance imaging of the head regions. This device incorporates advanced radio frequency technology housed in a closed, ergonomic package with many patient friendly features including a shorter coil length so that no part of the coil will be over the patients eyes, nose or mouth. The materials of construction and components are all identical to the predicate devices.

The tubular shaped coil is 13" OD x 9.9" ID x 10" L with a section removed from the bottom that is 60° of the coil circumference and 2" deep. The coil is attached to 2 rails that allow it to slide back and away from the patient, and then to be positioned with the patients head inside the tubular device. The back and sides of the coil will be placed over the center of the ears of the patient while the cut out front edge will be placed parallel with the eye brows.

The outer surfaces of the coil are manufactured from painted plastic polymer materials. These materials have been found to be biologically inert. These materials are routinely used in medical device construction and can be cleaned using mild bleach or alcohol as the customers will be instructed to do so.

The outer surfaces of the coil are manufactured from materials that are routinely used in medical device construction and can be cleaned using mild bleach or alcohol.

Features of the Insight Head Coil:

Imaging

- 2-channel quadrature design uses multiple elements that surround the head tissue
- Optimized for high speed imaging applications
- Compatible with Siemens and GE3T MRI systems
- High SNR

Ergonomics

- Large ID to accommodate a major percentage of patient population
- Ergonomically designed for patient comfort to minimize motion artifact
- Positioning accessories include an adjustable head support and retraction mechanism
- Attachable mirror to reduce patient claustrophobic response
- Complete lack of material in front of the patients face to reduce claustrophobic response.

6. Comparison with Legally Marketed Devices

The Insight Head Coil is substantially equivalent to the legally marketed devices listed below:

Model:	Magnetom Trio Head Coil
Manufacturer:	USA Instruments
510 (k) Number:	K021330

Model:	AIR Head Coil
Manufacturer:	Advanced Imaging Research
510 (k) Number:	K023929

Model:	TEM 3000 Head Coil
Manufacturer:	MR Instruments Inc.
510 (k) Number:	K040937

All of these head coils are intended for use in conjunction with a magnetic resonance scanner to produce diagnostic images of the head and neck tissues that can be interpreted by a radiologist.

The predicate devices are designed for use with various MR scanners as is the Insight Head Coil.

The Insight Head Coil is a quadrature transmit and receive coil for imaging the tissues of the head and neck. All of these head coils have an open coil design to optimize imaging of heads of various sizes.

7. Conclusions

The Insight Head Coil is substantially equivalent to the identified legally marketed devices. The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and planned verification and validation testing processes. The Insight Head Coil provides images comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 19 2006

Ms. Patricia A. Milbank
Regulatory Consultant
Insight Neuroimaging Systems LLC
11 Canterbury Street
WORCHESTER MA 01610

Re: K061281
Trade/Device Name: Insight Head Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: May 5, 2006
Received: May 9, 2006

Dear Ms. Milbank:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, 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/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

6 Indication(s) for Use Statement

510(k) Number: To be assigned by FDA K061281

Device Name: Insight Head Coil

Indications for Use:

The Insight Head Coil is a quadrature transmitting and receiving device used to produce magnetic resonance images of the head regions that can be interpreted by a trained radiologist. This device provides a closed, ergonomic package with many patient friendly features including a shorter coil length so that no part of the coil will be over the patient's eyes, nose or mouth.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061281