FEB 10 2014

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part §807.92.

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Date Prepared:	January 9, 2014

Device Name

Trade Name:	iMRI 1.5T A and iMRI 3T S
Common Name:	MRDD (Magnetic Resonance Diagnostic Device)
Classification Name:	System, Nuclear Magnetic Resonance Imaging (21 CFR §892.1000)
Product Code:	LNH

Predicate Devices:

iMRI 1.5T A system is substantially equivalent to the IMRIS Neuro II-SE MRI system. Siemens AGNETOM Aera is a reference device.

510(k)	Decision Date	Device Name	Manufacturer
K071099	May 22, 2007	Neuro II-SE Intra-operative Magnetic Resonance Imaging System	IMRIS Inc.
K101347	Oct 1, 2010	MAGNETOM Aera (Reference Device)	Siemens Medical Solutions USA, Inc.

iMRI 3T S system is substantially equivalent to the IMRIS Neuro III-SV MRI system. Siemens MAGNETOM Skyra is a reference device.

510(k)	Decision Date	Device Name	Manufacturer
K083137	Dec 16, 2008	Neuro III-SV Intra-operative Magnetic Resonance Imaging System	IMRIS Inc.
K101347	Oct 1, 2010	MAGNETOM Skyra (Reference Device)	Siemens Medical Solutions USA, Inc.

Device Description:

The IMRIS Intraoperative MRI systems (iMRI 1.5T A and iMRI 3T S) are a traditional MRI unit that has been suspended on an overhead rail system, and is designed to operate inside an RF shielded room to facilitate intra-operative and multi-room use. The magnet is normally situated in a diagnostic room until imaging is requested. For Diagnostic room purposes, the system retains the standard diagnostic features of an MRI system. The diagnostic room is separated from the intra-operative suite by sliding doors that are part of the facility structure.

The iMRI system (1.5T A/3T S) is a tool for radiologists and surgeons, used to acquire images for diagnostic, intra-operative or interventional procedures. For OR purposes, high-resolution images can be obtained immediately prior to surgical incision, intraoperative and after wound closure. The iMRI 1.5T A is based on the IMRIS Neuro II-SE predicate cleared under 510(k) K071099 and the Siemens MAGNETOM Aera/Skyra MRI system cleared under 510(k) K101347. The iMRI 3T S is based on the IMRIS Neuro III-SV cleared under 510(k) K083137 and the Siemens MAGNETOM Aera/Skyra MRI system cleared under 510(k) K101347. The major components of the iMRI systems are: the Siemens MAGNETOM MRI system with minor modifications; IMRIS Magnet Mover System, OR Table, RF coils and 3-pin head fixation device.

Intended Use:

The iMRI 1.5T A and 3T S are indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and / or spectra, and that displays the internal structure and / or function of the head, body or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical

parameters derived from the images and/or spectra when interpreted by trained physician yield information that may assist in diagnosis.

The iMRI 1.5T A and 3T S systems may also be used for imaging during intra-operative and interventional procedures when performed with MR safe devices or MR conditional devices approved for use with the MR scanner.

The iMRI 1.5T A and 3T S MRI systems may also be used for imaging in a multi-room suite.

Comparison with Predicate Devices:

The iMRI 1.5T A is based on the IMRIS Neuro II-SE predicate cleared under 510(k) K071099 and the iMRI 3T S is based on the IMRIS Neuro III-SV cleared under 510(k) K083137. The reference devices Siemens MAGNETOM Aera/Skyra MRI system are cleared under 510(k) K101347. There are no changes made to the Siemens' *syngo®* MR software in the iMRI systems. The iMRI 1.5T A/3T S MRI imaging system's software is the same as the Siemens MAGNETOM Aera/Skyra MRI System cleared under 510(k) K101347 and K121434. The iMRI 1.5T A/3T S intra-operative features, including the Magnet Mover Assembly, Intra-operative Coil and Head Fixation Device are substantially equivalent to the same intra-operative features of the predicate Neuro II-SE and Neuro III-SV. The iMRI system does not raise any new safety or effectiveness issues related to the use of a moving MRI system in an intra-operative setting.

Standards:

Recognition #	Identifier	Title
5-4	IEC 60601-1:1988+A1:1991+A2:1995	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
5-77	AAMI / ANSI ES60601-1:2005/C1:2009/A2:2010	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
5-53	IEC 60601-1-2:2007	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic compatibility - Requirements and Tests (Edition 3)
12-207	IEC 60601-2-33 :2010	MEDICAL ELECTRICAL EQUIPMENT Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
13-8	IEC 62304:2006	Medical device software - Software life cycle processes

Summary of Studies:

The iMRI systems (1.5T A and 3T S) have been designed to provide MRI imaging in an intra-operative setting in the same manner as the predicate Neuro systems (Neuro III–SV and Neuro II-SE System). The iMRI 3T S/1.5T A intra-operative features, including the Magnet Mover Assembly, OR Patient Table, Intra-operative Coil and Head Fixation Device are substantially equivalent to the same intra-operative features

of the predicate Neuro III-SV/ Neuro II-SE. The iMRI systems (1.5T A and3T S) do not raise any new safety or effectiveness issues related to the use of a moving MRI system in an intra-operative setting.

The iMRI systems (1.5T A and 3T S) MRI imaging system's software and hardware are substantially equivalent to the Siemens MAGNETOM Skyra and Aera. The iMRI systems (1.5T A and 3T S) do not raise any new safety issues related to static magnetic field effects, changing magnetic field effects, RF heating or acoustic noise or effectiveness issues related to specification volume, signal to noise, image uniformity, and geometric distortion, slice profile, thickness and gap, or high contrast spatial resolution.

Testing has been completed to verify the equivalence to the Siemens MAGNETOM Skyra and Aera System and to verify the safe and effective intra-operative operation of the iMRI systems (1.5T A and 3T S).

iMRI systems (1.5T A and 3T S) verification and validation supports a determination of substantial equivalence.

Summary of non-clinical data

Design Verification and Validation Test (Bench Testing)

The IMRIS iMRI systems passed the following tests and meets product specifications. IMRIS has performed a number of V&V tests as described in part 6 of this submission. The tests include

- IEC 60601-1 compliance
- IEC 60601-2 compliance
- IEC 60601-2-33 compliance
- Sample clinical images

Conclusion:

The iMRI 1.5T A is substantially equivalent to the predicate the IMRIS Neuro II-SE system (K071099) and the iMRI 3T S is substantially equivalent to the IMRIS Neuro III-SV system (K083137), based on the included studies and analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

IMRIS, INC.
C/O MARK JOB
1394 25TH STREET, NW
BUFFALO MN 55313

February 10, 2014

Re: K133692
Trade/Device Name: iMRI 1.5TA and iMRI 3.0TS
Regulation Number: 21 CFR 892.1000
Regulation Name: magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH
Dated: January 10, 2014
Received: January 14, 2014

Dear Mr. Job:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-

free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara For

Janine Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k133692

Device Name: iMRI 1.5T A and 3T S

Indications for Use:

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The iMRI 1.5T A and 3T S MRI systems may also be used for imaging in a multi-room suite.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) and Radiological Health (OIR)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 133692