K083137

DEC 16 2008

APPENDIX F 510(k) SUMMARY

F.1 GENERAL INFORMATION

Establishment:	IMRIS Inc.
Address:	100-1370 Sony Place Winnipeg, Manitoba Canada R3T 1N5
Registration Number:	3003807210
Contact Person:	Mrs. B. Newis Quality Assurance Representative email: bnewis@imris.com Phone: 1-204-480-7070 ext.7043 Fax: 1-204-480-7071
Date of Summary Preparation:	September 30, 2008
Device Name:	Neuro III-SV Intra-operative Magnetic Resonance Imaging System
Trade Name:	Neuro III-SV
Common Name:	MRDD (Magnetic Resonance Diagnostic Device)
Proprietary name:	Neuro III-SV
Classification name:	System, Nuclear Magnetic Resonance Imaging
Classification:	21 CFR 892.1000
Class:	Class II
Product Code:	LNH (Magnetic Resonance Imaging System)
Performance Standards:	None established under Section 514 of the Food, Drug and Cosmetic Act

F.2 INDICATIONS FOR USE

The IMRIS Neuro III-SV MRI system is indicated for use for the head and whole body.

F.3 INTENDED USE OF THE DEVICE

The Neuro III-SV Intra-operative MRI system is 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 and whole body. Depending on the region of interest, contrast agents may be used. These images and / or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The Neuro III-SV 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 Neuro III-SV may also be used for imaging in a multi-room suite.

F.4 DEVICE DESCRIPTION

The Neuro III-SV system is a traditional MRI unit that has been suspended on an overhead rail system to facilitate intra-operative use. The main components of the Neuro III-SV system are the MRI system assembly (including diagnostic RF coils), the magnet mover system, the OR Table assembly, Head Fixation Device and the Intra-operative Coil.

F.5 SAFETY AND EFFECTIVENESS

The Neuro III-SV has been designed to provide MRI imaging in an intra-operative setting in the same manner as the predicate Neuro II–SE System and predicate Neuro II-S devices. The Neuro III-SV 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 II-SE and predicate Neuro II-S. The Neuro III-SV does not raise any new safety or effectiveness issues related to the use of a moving MRI system in an intra-operative setting.

The Neuro III-SV MRI imaging system's software and hardware are substantially equivalent to the Siemens MAGNETOM Verio 3T MRI System. The Neuro III-SV does 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 Verio System and to verify the safe and effective intra-operative operation of the Neuro III-SV.

The Neuro III-SV Intra-operative Magnetic Resonance Imaging System is substantially equivalent to the Siemens MAGNETOM Verio; the IMRIS predicate Neuro II-SE and the predicate Neuro II-S imaging systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 6 2008

IMRIS, Inc.
% Mr. Thomas M. Tsakeris
President
Devices & Diagnostics Consulting Group, Inc.
16809 Briardale Road
ROCKVILLE MD 20855

Re: K083137
Trade/Device Name: Neuro III-SV Intra-operative Magnetic Resonance Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: October 10, 2008
Received: October 23, 2008

Dear Mr. Tsakeris:

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 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). 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 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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K083137

Device Name: Neuro III-SV Intra-operative Magnetic Resonance Imaging System

Indications For Use:

The Neuro III-SV Intra-operative MRI system is 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 and whole body. Depending on the region of interest, contrast agents may be used. These images and / or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

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The Neuro III-SV 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 807 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 K083137

(Per 21 CFR 801.109)
(Optional Format 1-2-96)