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510(k) SUMMARY FOR HC150/HC300

1. GENERAL INFORMATION

Establishment:	IMRIS Inc.
Address:	100-1370 Sony Place Winnipeg, Manitoba Canada, R3T 1N5
Registration Number:	3003807210
Contact Person:	Mr. Sanjay Shah QA and Regulatory Engineer Email: sshah@imris.com Phone: 1-204-480-7070, Fax: 1-204-480-7071
Date of Summary Preparation:	September 30, 2010
Device Name/Trade name	1.5T Head Coil (HC150) 3T Head Coil (HC300)
Classification Name:	Coil, magnetic resonance, specialty
Classification Panel:	Radiology
Classification (CFR section):	21 CFR 892.1000
Class:	Class II
Product Code:	MOS

2. INDICATION FOR USE

IMRIS Flex coils HC150 (1.5T Head coil) and HC300 (3T Head coil) are used in conjunction with respective MR Systems IMRIS 1.5T MAGNETOM and IMRIS 3T MAGNETOM as an imaging device for clinical procedures.

IMRIS Flex coils produce images of the human head and upper C-spine internal structures.

When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis and therapy options.

3. DEVICE DESCRIPTION

The IMRIS 1.5T Head Coil (HC150) is a receive-only eight channel phased array coil. The coil is divided into a bottom and a top array of 4 channels each. The HC150 is a pair of receive-only phased array coils designed for use with the IMRIS 1.5T system. The IMRIS 1.5T (Neuro II-SE) uses the Siemens MAGNETOM 1.5T MRI system (MAGNETOM Espree).

The IMRIS 3T Head Coil (HC300) is a receive-only eight channel phased array coil. The coil is divided into a bottom and a top array of 4 channels each. The HC300 is a pair of receive-only phased array coils designed for use with the IMRIS 3T system. The IMRIS 3T (Neuro III-SV) uses the Siemens MAGNETOM 3T MRI system (MAGNETOM Verio).

The IMRIS HC150/HC300 head coils balance surgical requirements with the MRI requirements to provide MR imaging in intra-operative and interventional procedures. Coils are used to acquire MR images of the head and upper C-spine during intra-operative /interventional

procedures. The IMRIS HC150/HC300 head coils can also be used as standard diagnostic head coils for diagnostic examinations.

4. SUBSTANTIALLY EQUIVALENT

HC150/HC300 coils are substantially equivalent to the 1.5T/3T Split Array Head (SAH) coil components of the following Medical device systems.

Name of the Device	510(k) Number	Date of Clearance
IMRIS iMRX system (SAH Coil-1.5T)	K091166	Sep 2, 2009
IMRIS 3T Intra-operative MRI System (Neuro III-SV) (SAH Coil-3T)	K083137	Dec 16, 2008
IMRIS 1.5T Intra-operative MRI System (Neuro II-SE) (SAH Coil-1.5T)	K061916 K071099	Aug 11, 2006 May 22, 2007

5. SAFETY & EFFECTIVENESS

The HC150/HC300 coils have the same intended use and indications for use as the IMRIS 1.5T SAH coil / 3T SAH coil. Performance data demonstrate safety and effectiveness of the HC150/HC300 with the new characteristics.

Signal to Noise Ratio (SNR) and image uniformity tests according to NEMA standard are performed for the new HC150/HC300 coils and the results presented in this submission show that they are equivalent with the predicate devices

The IMRIS coils HC150/HC300 verification/validation results and performance/safety standard results show that the device is safe and effective and substantially equivalent to the currently available predicate devices, the SAH coil 1.5T and SAH coil 3T.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

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

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Re: K103506
Trade/Device Name: HC150 (1.5T Head Coil) and HC300 (3T Head Coil)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 24, 2010
Received: November 29, 2010

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K103506

Device Name: HC150 (1.5T Head coil) and HC300 (3T Head coil)

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Prescription Use _____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 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 Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103506