K093044

MAR 1 3 2010

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Submitter Information

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44080-2371 ph: (330) 425-1313 fax: (330) 425-1410
Contact:	Douglas J. Thistlethwaite
Date:	9/23/09

Device Name

Classification Name:	System, Nuclear Magnetic Resonance Imaging
Classification Number:	90LNI
Trade/Proprietary Name:	Oasis MRI with Spectroscopy
Predicate Device(s):	Echelon MR Spectroscopy Package (K071506)

Device Intended Use

The Hitachi Oasis MRI with Spectroscopy is intended for use as a non-invasive diagnostic device that provides information based on relative concentrations of metabolites in body tissues. This NMR data in the form of spectra or spectral images reflect the NMR properties of proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and chemical shift. When interpreted by a trained medical practitioner, these spectral data provide information that can be useful in diagnosis determination.

This package is indicated for use as follows:

Anatomical Region: Head, whole body

Nuclei Excited: ^{1}H

Device Description

MR Spectroscopy is an imaging and analysis feature that can provide unique information about tissue within a human body. Spectroscopy can be used to complement or augment information and images obtained through other MR imaging and analysis techniques.

The acquisition of spectroscopic information is fundamentally the same as for other MR imaging techniques. For example, a modified spin echo sequence is used to collect data for one or more voxels of tissue. This data collection utilizes existing MR hardware and software, for example, the main magnetic field, gradient coils, RF transmitter, RF receiver coils, and memory or "K-Space".

The analysis of the collected data is what differentiates MR Spectroscopy from other more conventional MR imaging and analysis techniques. The data that is collected from the MR pulse sequence as described above is processed through MR spectroscopy algorithms. After computation and analysis on this data, information is displayed for the operator/reviewer. Spectroscopy data may be displayed in multiple ways, for example as data, graphs or images.

Safety and Effectiveness

The safety and effectiveness of this MR Spectroscopy Package is identical to the predicate device. The addition of this package does not impact the safety and effectiveness of the Oasis MRI system (K072279).

Conclusions

It is the opinion of Hitachi Medical Systems America, Inc. that the Oasis MRI system with Spectroscopy is substantially equivalent to the listed predicate device. The intended use is identical to the listed predicate device.

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

MAR 1 5 2010

Mr. Doug Thistlethwaite
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K093044
Trade/Device Name: Oasis MRI System with Spectroscopy
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNI
Dated: March 5, 2010
Received: March 8, 2010

Dear Mr. Thistlethwaite:

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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **k093044**

Device Name: Oasis MRI System with Spectroscopy

Indications for Use:

The Hitachi Oasis MRI with spectroscopy is intended for use as a non-invasive diagnostic device that provides information based on relative concentration of metabolites in body tissues. This NMR data in the form of spectra or spectral images reflect the NMR properties of proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and chemical shift. When interpreted by a trained medical practitioner, these spectral data provide information that can be useful in diagnosis determination.

Anatomical Region: Head, body, spine, extremities
Nucleus excited: proton
Diagnostic uses: T1, T2, proton density weighted imaging, diffusion weighted imaging, MR angiography, Image processing, spectroscopy, whole body

Prescription Use ____x___ (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 In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K093044