510(k) Summary:

K071506

JUN 2 8 2007

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:	5/28/2007

Device Name

Classification Name:	System, Nuclear Magnetic Resonance Imaging
Classification Number:	90LNI
Trade/Proprietary Name:	ECHELON MR Spectroscopy Package
Predicate Device(s):	Picker MR Spectroscopy Package (K991568)

Device Intended Use

The Hitachi Echelon MR Spectroscopy Package 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 making a diagnosis.

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 similar to the predicate device. The addition of this package does not impact the safety and effectiveness of the Echelon MRI system (*Cf.* K052172).

Conclusions

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 28 2007

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

Re: K071506
Trade/Device Name: Echelon MR Spectroscopy Package
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNI
Dated: May 28, 2007
Received: June 1, 2007

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 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

510(k) Number (if known): _____

Device Name: Echelon MR Spectroscopy Package

Indications for Use:

The Hitachi Echelon MR Spectroscopy Package 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 making a diagnosis.

Anatomical Region: Head, Whole Body

Nucleus excited: ^{1}H

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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071506