APR 3 0 2012

K113145

p 1/4

Submitter Information

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371 ph: (330) 425-1313 fax: (330) 963-0749
Contact:	Douglas J. Thistlethwaite
Date:	October 21, 2011

Device Name

Classification Name:	System, Nuclear Magnetic Resonance Imaging
Classification Number:	90LNH
Trade/Proprietary Name:	ECHELON Oval MRI System
Predicate Device(s):	ECHELON C Magnetic Resonance Imaging System (K083533)

Device Intended Use

The ECHELON Oval System is an imaging device and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images 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

Device Description

Function

The ECHELON OVAL is a Magnetic Resonance Imaging System that utilizes a 1.5 Tesla superconducting magnet in a gantry design. The design was based on the ECHELON MRI system. The ECHELON OVAL has been designed to enhance clinical utility as compared to the ECHELON by taking advantage of open architecture.

Scientific Concepts

Magnetic Resonance Imaging (MRI) is based on the fact that certain atomic nuclei have electromagnetic properties that cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nuclei currently used in magnetic resonance imaging. When placed in a static magnetic field, these nuclei assume a net orientation or alignment with the magnetic field, referred to as a net magnetization vector. The introduction of a short burst of radiofrequency (RF) excitation of a wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a re-orientation of the net magnetization vector. When the RF excitation is removed, the protons relax and return to their original vector. The rate of relaxation is exponential and varies with the character of the proton and its adjacent molecular environment. This re-orientation process is characterized by two exponential relaxation times, called T1 and T2.

A RF emission or echo that can be measured accompanies these relaxation events.

The emissions are used to develop a representation of the relaxation events in a three dimensional matrix. Spatial localization is encoded into the echoes by varying the RF excitation, applying appropriate magnetic field gradients in the x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of the NMR characteristics can be reconstructed by using image processing techniques similar to those used in computed tomography.

Physical and Performance Characteristics

MRI is capable of producing high quality anatomical images without the associated risks of ionizing radiation. The biological properties that contribute to MR image contrast are different from those responsible for x-ray image contrast. In MR imaging, difference in proton density, blood flow, and T1 and T2 relaxation times can all contribute to image contrast. By varying the pulse sequence characteristics, the resulting images can emphasize T1, T2, proton density, or the molecular diffusion of water or other proton containing molecules. And MR system has the function of measuring spectroscopy.

Device Technological Characteristics

The control and image processing hardware and the base elements of the system software are identical to the predicate device.

The ECHELON Oval is equivalent to the Echelon with the following exceptions:

- Gantry bore dimension is changed from circle with diameter 61cm to oval with 74cm x 65cm
- Maximum RF power is increased from 20 kW to 40 kW
- Maximum output current of gradient amplifier is increased from 550 A to 700 A
- AD converter of the MR signal is moved from the equipment room RFIP Cabinet to the gantry
- Patient table has the function of docking and undocking from the gantry
- Software operating system is changed to Windows 7 from Windows XP
- CPU platform is changed to Intel Core i5 3.33GHz from Intel Core2Duo 2.13GHz

Summary of Clinical/Non-Clinical Testing

Non-Clinical Testing

The ECHELON Oval was subjected to the following laboratory testing as outlined in the FDA MRI 510(k) guidance[1]:

MRI Test Standards

- NEMA MS 1, Determination of Signal-to-noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- NEMA MS 2, Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 3, Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- NEMA MS 4, Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices
- NEMA MS 5, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging

[1] *Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices*, FDA, November 14, 1998

- NEMA MS 7, Measurement Procedure for Time-Varying Gradient Fields (dB/dt) for Diagnostic Magnetic Resonance Imaging Devices
- NEMA MS 8, Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems

Additional Test Standards

- IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC 60601-1-1, Medical Electrical Equipment – Part 1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2, General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-4, Medical Electrical Equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems
- IEC 60601-2-33, Medical Electrical Equipment, Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
- IEC 62304, Medical device software - Software life cycle processes

Additional Non-clinical Testing

Additional laboratory testing included:

- High Contrast Spatial Resolution
- Estimation of the Ratio of Peak Local (10g average) SAR Values to Whole-Body SAR (numerical simulation)

Clinical Testing

The Echelon Oval submission includes sample clinical imaging of the head, torso, and extremities using all anatomy coils, as specified in the FDA MRI 510(k) guidance referenced above.

Conclusions

It is the opinion of Hitachi Medical Systems America, Inc. the ECHELON Oval MRI System is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the ECHELON C Magnetic Resonance Imaging System (K083533).

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

APR 30 2012

Mr. Doug Thistlethwaite
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087-2371

Re: K113145
Trade/Device Name: ECHELON Oval MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI, and MOS
Dated: March 15, 2012
Received: March 16, 2012

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,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K113145

Indications for Use

510(k) Number (if known): K113145

Device Name: ECHELON Oval MRI System

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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___ 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 In Vitro Diagnostic Devices (OIVD)

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

510(k) Number K113145