DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

March 2, 2015

Re: K142734
Trade/Device Name: Trillium Oval MR System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: January 6, 2015
Received: January 7, 2015

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K142734

Device Name: TRILLIUM OVAL MR System

Indications for Use:

The TRILLIUM Oval MRI 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
Whole Body

Prescription Use ✓ 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 OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

_____
Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k)_____

Section 5

510(k) Summary

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:	September 17, 2014

Device Name

Classification Name:	System, Nuclear Magnetic Resonance Imaging
Classification Number:	90LNH
Trade/Proprietary Name:	TRILLIUM Oval MRI System
Predicate Device(s):	ECHELON Oval MRI System (K113145)

Device Intended Use

The TRILLIUM 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
- Whole Body

Device Description

Function

The TRILLIUM OVAL is a Magnetic Resonance Imaging System that utilizes a 2.9 Tesla superconducting magnet in a gantry design. The design was based on the ECHELON Oval MRI system. The TRILLIUM OVAL has been designed to enhance clinical utility as compared to the ECHELON Oval by taking advantage of the stronger magnetic field and stronger gradient field and slew rate.

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 TRILLIUM Oval is equivalent to the Echelon Oval with the following exceptions:

- Static magnetic field is changed to 2.9T
- Maximum Gradient strength and slew rate are upgraded to 40mT/m and 200T/m/s with a twin gradient amplifier of 600A at 1400V
- RF transmitter coil has 4 feeding ports and a 4 channel RF amplifier at 10kW each. Phase and amplitude can be controlled on each channel.
- Newer reconstruction CPUs can reduce processing time of imaging
- Monitoring hardware and software manages the SAR during scan

Summary of Clinical/Non-Clinical Testing

Non-Clinical Testing

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

MRI Test Standards

- NEMA MS 1-2008, Determination of Signal-to-noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- NEMA MS 2-2008, Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 3-2008, Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- NEMA MS 4-2010, Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices
- NEMA MS 5-2010, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- NEMA MS 7-1993 (Revision 1998), Measurement Procedure for Time-Varying Gradient Fields (dB/dt) for Diagnostic Magnetic Resonance Imaging Devices
- NEMA MS 8-2008, Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems

Additional Test Standards (to be completed)

- AAMI / ANSI ES60601-1:2005/(R) 2012 and A1:2012, c1:2009/(r) 2012 and a2:2010/(r) 2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod).
- IEC 60601-1-2 Edition 3:2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.
- IEC 60601-2-33 Edition 3.1 2013-04, medical electrical equipment - part 2-33: particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic.
- IEC 62304 First edition 2006-05, medical device software - software life cycle processes.

Additional Non-clinical Testing

Additional laboratory testing included:

- Validation of Electromagnetic Simulation Summary
- B1 Map Comparison between FDTD Simulations and Experiments
- Validation for SAR Simulation
- Uncertainty analysis for local SAR
- Comparison of local SAR between TRILLIUM OVAL and ECEHLON C
- Worst case analysis of local SAR in TRILLIUM OVAL
- Simulation Results: SAR Hugo Model
- Simulation Results: SAR Fats Model
- Simulation Results: SAR Hanako Model
- Simulation Results: SAR Roberta Model

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

Clinical Testing

The TRILLIUM 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 TRILLIUM Oval MRI System is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the ECHELON Oval MRI System (K113145).