DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

March 31, 2016

Re: K153547
Trade/Device Name: ECHELON Oval V 5.1 MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 2, 2016
Received: March 3, 2016

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153547

Device Name
ECHELON OVAL V5.1 MRI system

Indications for Use *(Describe)*
The ECHELON 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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5

510(k) Summary

Submitter Information

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
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Date:	November 30, 2015

Device Name

Regulation Number:	892.1000
Regulation Name:	Magnetic resonance diagnostic device
Product Code	LNH
Class	2
Panel	Radiology
Trade/Proprietary Name:	ECHELON Oval V5.1 MRI System
Predicate Device(s):	ECHELON Oval V5.0 MRI System (K151015)

Device Intended Use

The ECHELON Oval V5.1 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 ECHELON OVAL V5.1 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.

Performance Evaluation

There is no change from the previous predicate device that would affect performance.

The ECHELON OVAL V5.1 MRI is equivalent to the ECHELON OVAL V5.0 MRI (K151015) with the following exceptions:

- 32ch in RF receiver channel is added to product specification.
- Xeon 3.5GHz in CPU platform is added to product specification.
- Reconstruction configuration hardware is changed to from the TIP to the FARCON.
- Coil mode of Spine coil is added for over 16ch receiver channels.
- The Soft Sound function in pulse sequences is added to functional specification.

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 includes V5.1 software is substantially equivalent to the ECHELON OVAL V5.0 (K151015). See tables below.

The technological characteristics in regards to hardware of the ECHELON Oval MRI System and the predicate are listed in Table 1.

Table 1 Comparison: Hardware

ITEM		ECHELON OVAL V5.0 (K151015) PREDICATE	ECHELON OVAL V5.1	DIFFERENCE ANALYSIS
System	Standards Met	NEMA: MS 1, MS 2, MS 3, MS 4, MS 5, MS 8, IEC: 60601-1, 60601-1-2, 60601-2-33, 62304	NEMA: MS 1, MS 2, MS 3, MS 4, MS 5, MS 8, IEC: 60601-1, 60601-1-2, 60601-2-33, 62304	No
Magnet and Gantry	Type and Field Strength	Super-conducting magnet, horizontal bore, 1.5 Tesla	Super-conducting magnet, horizontal bore, 1.5 Tesla	No
	Resonant Frequency	63.86 MHz	63.86MHz	No
Gradient System	Gradient Strength	34mT/m	34mT/m	No
	Slew Rate	150 T/m/sec	150 T/m/sec	No
	Rise Time	227µsec to 34mT/m	227µsec to 34mT/m	No
	Audible Noise (MCAN)			
	Ambient	58 dBA	58 dBA	No
	Lpeak	125 dBA	125 dBA	No
	Leq	117 dB	117 dBA	No
RF System	Transmitter channels	2	2	No
	Peak Envelop Power	40 kW	40 kW	No
	Duty Cycle	100% (Gating max), 12.5% at full power	100% (Gating max), 12.5% at full power	No
	RF receiver channel	16	16, 32	See Table 2

The hardware differences from the ECHELON Oval MRI System to the predicate device are analyzed in Table 2.

Table 2 Hardware Comparison Analysis

FDA Requirements	Analyze why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)).			
Device Modification Summary	• 32ch in RF receiver channel is added to product specification. • Xeon 3.5GHz in CPU platform is added to product specification. • Reconstruction configuration hardware is changed to from the TIP and 1 PC to the FARCON and 2 PCs.			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
HITACHI Rationale Statement	Modified specification doesn't constitute a new intended use. There are no significant changes in technological characteristics. For safety, gradient system and RF system is controlled according to same regulation as ECHELON Oval V5.0 (K151015). So, safety and effectively of the device are same as ECHELON Oval V5.0 (K151015)			

The technological characteristics in regards to coils of the ECHELON Oval MRI System and the predicate are listed in Table 3.

Table 3 Comparison: RF Coils

ITEM		ECHELON OVAL V5.0 (K151015) PREDICATE	ECHELON OVAL	DIFFERENCE ANALYSIS
RF Coils	Transmit Coil	T/R Body	T/R Body	No
	Receiver Coils	WIT Posterior Head/Neck coil, WIT Anterior Head attachment	WIT Posterior Head/Neck coil, WIT Anterior Head attachment	No
		WIT Torso coil	WIT Torso coil	No
		Extremity coil (Knee)	Extremity coil (Knee)	No
		WIT Anterior Neck attachment	WIT Anterior Neck attachment	No
		Hand/Wrist coil	Hand/Wrist coil	No
		WIT Anterior NV attachment	WIT Anterior NV attachment	No
		Breast	Breast	No
		MP coil 140A, B	MP coil 140A, B	No
		Shoulder	Shoulder	No
		WIT Spine coil 12	WIT Spine coil 12	No
		WIT Spine coil 8	WIT Spine coil 8	No
		Foot/Ankle	Foot/Ankle	No
		Flexible Extremity (Long Bone)	Flexible Extremity (Long Bone)	No
		WIT Cardiac	WIT Cardiac	No
		PV	PV	No

The coil differences from the ECHELON Oval MRI System to the predicate device are analyzed in Table 4.

Table 4 Coil Comparison Analysis

FDA Requirements	Analyze why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)).			
Device Modification Summary	The performance and technological characteristics of the coils are the same as ECHELON Oval V5.0 (K151015).			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
HITACHI Rationale Statement	Modified functions don't constitute a new intended use. There are no significant changes in technological characteristics. During transmitter coil operation, RF Coils are de-resonated by same scheme as ECHELON Oval V5.0 (K151015).			

The technological characteristics in regards to changes in functionality of the ECHELON Oval MRI System as compared to the predicate are listed in Table 5.

Table 5 Comparison: Functionality

ITEM	DIFFERENCES	ANALYSIS
Operating System	None	No
CPU Platform	Core i3 3.5GHz in CPU platform is also available on ECHELON Oval V5.1.	See Table 6
Application Software	Going from V5.0A to V5.1A	See Table 6
Scan Tasks	None	No
2D Processing Tasks	Vivid Image is available	See Table 6
3D Processing Tasks	None	No
Analysis Tasks	None	No
Maintenance Tasks	None	No
Viewport Tools	None	No
Film, Archive Tools	None	No
Network Tools	None	No
Protocol Enhancements	ASL perfusion (pCASL) is available, NCC function is available.	See Table 6
Pulse Sequences	2D Soft FSE, 2D Soft FIR, 2D Soft SE, 3D Soft TOF is available	See Table 6

The functionality differences from the ECHELON Oval MRI System to the predicate device are analyzed in

Table 6 Functionality Comparison Analysis

FDA Requirements	Analyze why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)).			
Device Modification Summary	• Soft FSE, Soft FIR, Soft SE and Soft TOF, which are used for the Protocol Enhancements of Soft Sound, in pulse sequences category are added to functional specification. • Xeon 3.5GHz in CPU platform is added to product specification. • ASL Perfusion (pCASL) in the protocol enhancement is added to product specification. • VIVID image which enhances image quality in the 2D processing tasks is added to product specification.. • NCC function for improvement of MAC coil reconstruction image quality in the protocol enhancements is added to product specification.			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
HITACHI Rationale Statement	Modified functions do not constitute a new intended use. There are no significant changes in technological characteristics. For safety, pulse sequences are controlled according to same safety limits as ECHELON Oval V5.0 (K151015). So safety and effectivity of the device are equivalent to the ECHELON Oval V5.0 (K151015).			

Substantial Equivalence

A summary decision was based on analysis of Table 7.

Table 7 Rationale Analysis: ECHELON Oval V5.1 MRI vs. Predicate

ITEM	Overall Rationale Analysis
Hardware	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics, safety and effectiveness.
Coils	Modified functions don't constitute a new intended use. There are no significant changes in technological characteristics, safety and effectiveness.
Functionality	Enhanced features do not constitute a new intended use. There are no significant changes in technological characteristics, safety and effectiveness. The feature set of the device is generally equivalent to the Predicate.

Therefore, based on a thorough analysis and comparison of the functions, scientific concepts, physical and performance characteristics, performance comparison and technological characteristics, the proposed ECHELON Oval MRI is considered substantially equivalent to the currently marketed predicate device (ECHELON Oval V5.0 MRI System (K151015)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Summary of Non-Clinical Testing

The revisions to the ECHELON Oval V5.1 MRI System software will have no effect on the standards tests which were conducted on the ECHELON Oval V5.0 MRI System (K151015) and included in the original submission.

Therefore, ECHELON Oval MRI System is in conformance with the applicable parts of the following 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 8-2008, Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems
- 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.

In addition, tests were conducted on the new feature of the ECHELON Oval V5.1 MRI System, they include:

- **Soft Sound**
  Test results confirm the acoustic sound pressure levels of conventional sequences and soft sound sequences.

Summary of Clinical Testing

There is no change from the previous predicate device that would affect clinical performance.

Conclusions

It is the opinion of Hitachi Medical Systems America, Inc. the ECHELON Oval V5.1 MRI System is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the ECHELON Oval V5.0 MRI System (K151015).