Hitachi Healthcare Americas Corporation
Doug Thistlethwaite
Manager of Regulatory Affairs
1959 Summit Commerce Park
Twinsburg, Ohio 44087

January 11, 2018

Re: K172110
Trade/Device Name: ECHELON OVAL V6.0A MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: November 30, 2017
Received: December 01 2017

Dear Doug 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Robert A. 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)*
K172110

Device Name
ECHELON OVAL V6.0A 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 Healthcare Americas 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
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Date:	June 14, 2017

Subject Device Name

Trade/Proprietary Name:	ECHELON OVAL V6.0A MRI system
Regulation Number:	21 CFR 892.1000
Regulation Name:	System, Nuclear Magnetic Resonance Imaging
Product Code	LNH
Class	2
Panel	Radiology

Predicate Device Name

Predicate Device(s):	ECHELON OVAL V5.1 MRI System (K153547)
Regulation Number:	21 CFR 892.1000
Regulation Name:	System, Nuclear Magnetic Resonance Imaging
Product Code	LNH
Class	2
Panel	Radiology

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
Whole Body

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.

Performance Evaluation

The ECHELON OVAL V6.0A MRI System is only a software update with new and improved features.

Therefore, a clinical and performance evaluation was conducted on the new features which include:

- HiMAR
- QSM
- Computed DWI

HiMAR can be used for reduction of metal artifacts around passive MR Conditional implants.

In addition, a clinical and performance evaluation was conducted on the improved features which include:

- Soft Sound Package
- Advanced contrast enhanced abdominal imaging
- ASL-Perfusion (GRASE)
- R2* Map Analysis
- Cine-PC Analysis

A rationale analysis was then conducted and the results are contained in Table 1.

Table 1 Performance Analysis

Testing Type	Rationale Analysis
Performance Testing - Bench	Performance bench testing was conducted on the applicable new and improved features. Test data confirmed that each new and improved feature perform as intended for diagnostic use.
Performance Testing - Clinical	Clinical image examples are provided for each applicable new and improved feature and that we judged to be sufficient to evaluate clinical usability. In addition, a radiologist validated that the clinical images have acceptable image quality for clinical use.

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 V6.0A MRI system software is substantially equivalent to the ECHELON OVAL V5.1 (K153547). See tables below.

The technological characteristics in regards to hardware of the ECHELON OVAL V6.0A MRI system and the predicate are listed in Table 2.

Table 2 Comparison: Hardware

ITEM		PREDICATE DEVICE	SUBJECT DEVICE	DIFFERENCE
		ECHELON OVAL V5.1 (K153547)	ECHELON OVAL V6.0A	
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, 32	16, 32	No

The hardware differences from the ECHELON OVAL V6.0A MRI system to the predicate device are analyzed in Table 3.

Table 3 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	There are no significant hardware changes that affect technological characteristics and safety.			
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 V5.1 (K153547). So, safety and effectively of the device are same as ECHELON Oval V5.1 (K153547)			

The technological characteristics in regards to coils of the ECHELON OVAL V6.0A MRI system and the predicate are listed in Table 4.

Table 4 Comparison: RF Coils

ITEM		PREDICATE DEVICE	SUBJECT DEVICE	DIFFERENCE
		ECHELON OVAL V5.1 (K153547)	ECHELON OVAL V6.0A	
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 Posterior Head/Neck coil B	See Table 5
		WIT Torso coil	WIT Torso coil	No
			WIT Torso coil 12	See Table 5
			WIT Torso coil 8	See Table 5
		Extremity coil (Knee)	Extremity coil (Knee)	No
		WIT Anterior Neck attachment	WIT Anterior Neck attachment	No
			WIT Anterior Neck attachment B	
		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
			Micro coil (S) A, B	See Table 5
		Shoulder	Shoulder	No
			Shoulder coil 8	See Table 5
		WIT Spine coil 12	WIT Spine coil 12	No
			WIT Spine coil A	See Table 5
		WIT Spine coil 8	WIT Spine coil 8	No
			WIT Spine coil B	See Table 5
		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 V6.0A MRI system to the predicate device are analyzed in Table 5.

Table 5 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	WIT Posterior Head/Neck coil B, WIT Anterior Neck attachment B, WIT Spine coil A, WIT Spine coil B, Micro coil (S) A, B, Shoulder coil 8, WIT Torso coil 12 and WIT Torso coil 8 are added. The performance or safety and effectiveness are the same as WIT Posterior Head/Neck coil, WIT Anterior Neck attachment, WIT Spine coil 12, WIT Spine coil 8, MP coil 140A, B, Shoulder and WIT Torso coil for ECHELON Oval V5.1 (K153547).			
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 V5.1 (K153547).			

The technological characteristics in regards to changes in functionality of the ECHELON Oval MRI System as compared to the predicate are listed in Table 6.

Table 6 Comparison: Functionality

ITEM	DIFFERENCES	ANALYSIS
Operating System	None	No
CPU Platform	None	No
Application Software	Going from V5.1A to V6.0A	See Table 7
Scan Tasks	RAPID capability is changed to 4.0 per a direction (16.0 per 2 dir.)	See Table 7
2D Processing Tasks	Image Division, and R2/R2* calculation are available.	See Table 7
3D Processing Tasks	None	No
Analysis Tasks	Computed DWI and volume flow analysis are available.	See Table 7
Maintenance Tasks	None	No
Viewport Tools	None	No
Film, Archive Tools	None	No
Network Tools	None	No
Protocol Enhancements	RADAR (2D Soft GE, 2D Soft FSE, 2D Soft FIR, 2D Soft SE, and 3D Soft TOF), Soft Sound (2D Soft FSE (Rephase: off), 2D Soft FSE (Rephase:Slice), 2D Soft FSE (RADAR), 2D Soft FIR (RADAR), 2D Soft SE (RADAR), 3D Soft TOF (RADAR), 2D Soft GE, 2D Soft GE (RADAR), and 2D Soft SARGE), ASL-Perfusion (GRASE), Advanced contrast enhanced abdominal imaging, , HiMAR, and QSM are available.	See Table 7
Pulse Sequences	2D Soft GE, 2D Soft SARGE, and 3D GRASE are available.	See Table 7

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

Table 7 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	• Image Division, and R2/R2* calculation of Parameter Analysis in the 2D Processing Tasks are added to product specification. • Computed DWI of DWI Analysis and volume flow of Velocity Analysis in the Analysis Tasks category are added to product specification. • 2D Soft GE, 2D Soft FSE, 2D Soft FIR, 2D Soft SE, and 3D Soft TOF of RADAR in the Protocol Enhancements category are added to product specification. • 2D Soft FSE (Rephase: off), 2D Soft FSE (Rephase:Slice), 2D Soft FSE (RADAR), 2D Soft FIR (RADAR), 2D Soft SE (RADAR), 3D Soft TOF (RADAR), 2D Soft GE, 2D Soft GE (RADAR), and 2D Soft SARGE of Soft Sound in the Protocol Enhancements category are added to product specification. • ASL-Perfusion (GRASE), Advanced contrast enhanced abdominal imaging, HiMAR, and QSM in the Protocol Enhancements category are added to product specification. • Soft GE and Soft SARGE, which are used for the Protocol Enhancements of Soft Sound, and GRASE, which are used for the Protocol Enhancements of ASL-Perfusion (GRASE) in pulse sequences category are added to functional 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 V5.1 (K153547). So safety and effectivity of the device are equivalent to the ECHELON Oval V5.1 (K153547).			

Substantial Equivalence

A summary decision was based on analysis of Table 8.

Table 8 Rationale Analysis: ECHELON Oval 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 V5.1 MRI System (K153547)) 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 MRI System software will have no effect on the standards tests which were conducted on the ECHELON Oval V5.1 MRI System (K153547) 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 and improved features of the ECHELON OVAL V6.0A MRI system, they include:

- Test Report: ASL-Perfusion (GRASE)
- Test Report: Advanced contrast enhanced abdominal imaging
- Test Report: Cine-PC Analysis
- Test Report: Computed DWI
- Test Report: HiMAR
- Test Report: QSM
- Test Report: R2* Map Analysis
- Test Report: Soft Sound Package

Summary of Clinical Testing

Clinical images were collected and analyzed, to ensure that images from the new features meet user needs.

As a result of the analysis:

Testing Type	Rationale Analysis
Performance Testing - Clinical	Clinical image examples are provided for each applicable new and improved feature and that we judged to be sufficient to evaluate clinical usability. In addition, a radiologist validated that the clinical images have acceptable image quality for clinical use.

Conclusions

It is the opinion of Hitachi, the ECHELON OVAL V6.0A MRI system is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the ECHELON Oval V5.1 MRI System (K153547).