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

July 29, 2015

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

Re: K151015
Trade/Device Name: ECHELON Oval V5.0 MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH and LNI
Dated: July 1, 2015
Received: July 6, 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,

For

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

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)*
K151015

Device Name
ECHELON OVAL V5.0 MRI system

Indications for Use *(Describe)*

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

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
Contact:	Douglas J. Thistlethwaite
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Date:	April 13, 2015

Device Name

Regulation Number:	892.1000
Regulation Name:	System, Nuclear Magnetic Resonance Imaging
Product Code	LNH
Class	2
Panel	Radiology
Trade/Proprietary Name:	ECHELON Oval V5.0 MRI System
Predicate Device(s):	ECHELON Oval MRI System (K113145)

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

Being the ECHELON Oval V5.0 MRI System is only a software update with new features, a clinical and performance evaluation was conducted on only the new features which include:

- ASL-Perfusion
- Beam Sat VASC-ASL
- Breast MRS
- Enhanced PC
- Fat and water separation scan (FSE, RSSG, GE)
- k-RAPID
- Multi b and DKI
- opFSE / opFIR
- PBSG
- RADAR-GE/TOF
- T2* RelaxMap

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

Table 1 Performance Analysis

Testing Type	Rationale Analysis
Performance Testing - Clinical	We provide clinical image examples for each new feature and 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.
Performance Testing - Bench	We generated bench data for each of the new features. We confirmed that each new feature performs as intended for diagnostic 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 includes V5.0 software is substantially equivalent to the ECHELON OVAL (K113145). See tables below.

The technological characteristics in regards to hardware of the ECHELON Oval V5.0 MRI System and the predicate are listed in Table 2.

Table 2 Comparison: Hardware

ITEM		ECHELON OVAL (K113145) PREDICATE	ECHELON OVAL V 5.0	DIFFERENCE ANALYSIS
System	Standards Met	NEMA: MS 1, MS 2, MS 3, MS 4, MS 5, MS 8, IEC: 60601-1, 60601-1-1, 60601-1-2, 60601-1-4, 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	56 dBA	58 dBA	See Table 3
	Lpeak	121 dBA	125 dBA	See Table 3
	Leq	119 dB	117 dBA	See Table 3
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	No

The hardware differences from the ECHELON Oval V5.0 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 (K113145). So, safety and effectively of the device are same as ECHELON OVAL (K113145)			

The technological characteristics in regards to coils of the ECHELON Oval V5.0 MRI System and the predicate are listed in Table 4.

Table 4 Comparison: RF Coils

ITEM		ECHELON OVAL (K113145) PREDICATE	ECHELON OVAL V 5.0	DIFFERENCE ANALYSIS
RF Coils	Transmit Coil	T/R Body	T/R Body	No
	Receiver Coils	RAPID Posterior/Anterior Head	WIT Posterior Head/Neck coil, WIT Anterior Head attachment	See Table 5
		RAPID Anterior Body	WIT Torso coil	See Table 5
		RAPID Extremity (Knee)	Extremity coil (Knee)	See Table 5
		RAPID Anterior Neck	WIT Anterior Neck attachment	See Table 5
		RAPID Extremity(S) (Hand/Wrist)	Hand/Wrist coil	See Table 5
		RAPID Anterior NV	WIT Anterior NV attachment	See Table 5
		RAPID Breast	Breast	See Table 5
		Multi-purpose	MP coil 140A, B	See Table 5
		RAPID Shoulder	Shoulder	See Table 5
		RAPID Back A	WIT Spine coil 12	See Table 5
		RAPID Back B	WIT Spine coil 8	See Table 5
		RAPID Foot/Ankle	Foot/Ankle	See Table 5
		RAPID Long Bone	Flexible Extremity (Long Bone)	See Table 5
		RAPID Cardiac	WIT Cardiac	See Table 5
		RAPID PV	PV	See Table 5

The coil differences from the ECHELON Oval V5.0 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	Some coil names are changed. The performance and technological characteristics of the coils are the same as ECHELON OVAL (K113145).			
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 (K113145).			

The technological characteristics in regards to changes in functionality of the ECHELON Oval V5.0 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 V4.0A to V5.0A	See Table 7
Scan Tasks	None	No
2D Processing Tasks	Only difference is T2* calculation is now available on ECHELON Oval V5.0.	See Table 7
3D Processing Tasks	None	No
Analysis Tasks	Only change is DEC-FA, AD, RD, MK, AK, RK, and FAK Maps with DWI Analysis are now available on ECHELON Oval V5.0.	See Table 7
Maintenance Tasks	None	No
Viewport Tools	None	No
Film, Archive Tools	None	No
Network Tools	None	No
Protocol Enhancements	Only change is Multi-b measurement, k-RAPID, T2* Relax Map, BeamSat VASC-ASL, RADAR (2DGE, 3D GE, 2D TOF, and 3D TOF), ASL-Perfusion, Enhanced PC (improvement of Cine PC), and Breast MRS are now available on ECHELON Oval V5.0.	See Table 7
Pulse Sequences	Only change is 2D Spoiled SARGE Fat Water Separation (2D FATSEPRSSG), 3D Spoiled SARGE Fat Water Separation (3D FATSEPRSSG), 2D Fast Spin Echo Fat Water Separation (2D FATSEPFSE), 2D Gradient Echo Fat Water Separation (2D FATSEPGE), 3D Gradient Echo Fat Water Separation (3D FATSEPGE), 2D Fast Spin Echo (2D opFSE), 2D Fast Spin Echo (2D opFIR), 2D Phase Balanced SARGE (2D PBSG), and 3D Phase Balanced SARGE (3D PBSG) are now available on ECHELON Oval V5.0.	See Table 7

The functionality differences from the ECHELON Oval V5.0 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	2D Processing Tasks T2* Calculation - Adds the ability to obtain T2* maps as opposed to previous software. Benefits areas such as liver and cartilage imaging. Analysis Tasks DWI Analysis- New Maps are added and allow for advanced evaluation of diffusion tensor and diffusion kurtosis imaging. Protocol Enhancements k-RAPID - K-space based parallel imaging. Reduces the occurrence of wrap artifacts. T2* RelaxMap - Adds the ability to obtain T2* maps as opposed to previous software. Benefits areas such as liver and cartilage imaging. BeamSat VASC-ASL - Cylindrical preset pulse added to current VASC-ASL sequence. Benefit is to selectively saturate a target vascular structure. ASL-Perfusion - Non-contrast brain perfusion. pASL based gradient echo EPI sequence. Enhanced PC - Reduces minimum TR/TE and adds RAPID capability. Breast MRS - Added single voxel breast spectroscopy Multi-b measurement - Gives the ability to acquire more than one B factor in one scan which saves time with no change in image quality. RADAR – 2D/3D GE and 2D/3D TOF pulse sequences can now use RADAR motion correction.

	Pulse Sequences 2D/3D FatSepRSSG - TE can be adjusted as opposed to a fixed TE in the previous software. Single 2pt. was added which gives the benefit of higher resolution scans. 2D FatSepFSE - Inner Echo time is now adjustable as opposed to the previous version of software. Single 2pt. was added which gives the benefit of higher resolution scans. 2D/3D FatSepGE – New, allows for T2* weighted imaging. 2D opFSE - Improved SNR, less artifacts, makes images less grainy than conventional FSE. 2D opFIR - Improved SNR, less artifacts, makes images less grainy than conventional FIR. 2D/3D PBSG - BASG sequence acquired at two different RF phases, resulting in decreased banding artifacts.			
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 (K113145). So safety and effectivity of the device are equivalent to the ECHELON OVAL (K113145).			

Substantial Equivalence

A summary decision was based on analysis of Table 8.

Table 8 Rationale Analysis: ECHELON Oval V5.0 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 V5.0 MRI is considered substantially equivalent to the currently marketed predicate device (ECHELON Oval MRI System (K113145)) 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 V5.0 MRI System software will have no effect on the standards tests which were conducted on the ECHELON Oval MRI System (K113145) and included in the original submission.

Therefore, ECHELON Oval V5.0 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 features of the ECHELON Oval V5.0 MRI System, they include:

- **ASL-Perfusion**

  Test results confirm ASL-Perfusion acquires perfusion images using labeled blood flowing into the brain tissue without Contrast-Enhanced both in phantom simulations and clinical results.

- **Beam Sat VASC-ASL**

  Test results confirm Beam Sat improves the visibility of the portal vein in making MIP images both in phantom simulations and clinical results.

- **Breast MRS**

  Test results from phantom simulations and clinical results confirm MRS (Magnetic Resonance Spectroscopy) acquires the magnetic resonance signal of in vivo metabolites through chemical shift phenomenon and can detect Choline as metabolite in the breast area.

- **Enhanced PC**

  Test results from phantom simulations and clinical results indicate a reduction in scan time of phase contrast (PC) sequence in 2D and 3D by shorting the TR by optimizing velocity encode gradient and applied parallel imaging (RAPID). As a result of this improvement, we can shorten scan time of “4D flow” which is time-resolved (CINE) three-dimensional (3D) spatial encoding combined with three-directional velocity-encoded phase contrast MRI.

- **Fat and water separation scan (FSE, RSSG, GE)**

  Test results from phantom simulations and clinical results indicate reliable and uniform fat suppression by utilizing the difference between resonant frequencies due to chemical shift of water protons and fat protons to obtain a water image and a fat image. The chemical shift of a water signal and a fat signal receives two echo signals at the timing which becomes an in-phase and an out-of-phase. By adding and subtracting it, a water image and a fat image are simultaneously acquirable.

- **k-RAPID**

  Test results from phantom simulations and clinical results indicate that k-space parallel imaging technique accelerates the scan by acquiring k-space data with skipped phase encoding and skipped position which is filled with estimated data by the interpolation of neighboring data.

- **Multi b and DKI**

  Test results from phantom simulations and clinical results confirm Multi b DKI images can be acquired in one scan utilizing Tensor 15 and Tensor 30 being added to the number of MPG Axes. Diffusion Kurtosis Imaging (DKI) is the diffusion-weighted imaging technique in restriction.

- **opFSE / opFIR**

  Test results from phantom simulations and clinical results confirm by deriving opFSE and opFIR sequence from the primeFSE and primeFIR image quality is improved.

- **PBSG**

  Test results from phantom simulations and clinical results confirm PBSG which is a sequence based on BASG sequence improves to mitigate the dark band artifact which is unique to BASG sequence. The PBSG sequence makes it possible to acquire BASG images under the condition of inhomogeneous magnetic field with less band artifact.

- **RADAR-GE/TOF**

  Test results from phantom simulations and clinical results confirm the RADAR measurement feature is functioning with the GE and TOF sequence.

- **T2* RelaxMap**

  Test results from phantom simulations and clinical results confirm that T2* relaxation time can be mapped on morphological image in color by using T2* RelaxMap function. The T2* RelaxMap function consists of (a) acquisition of multi-echo images (up to 32) and (b) analysis of T2* relaxation time.

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	We provide clinical image examples for each new feature and 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 Medical Systems America, Inc. the ECHELON Oval V5.0 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).