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

May 20, 2016

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

Re: K160152
Trade/Device Name: Trillium Oval V5.1 MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 18, 2016
Received: April 19, 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,

For

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)*

K160152

Device Name

TRILLIUM Oval V5.1 MRI system

Indications for Use *(Describe)*

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

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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E-mail:	thistlethwaited@hitachimed.com
Date:	December 4, 2015

Device Name

Regulation Number:	892.1000
Regulation Name:	Magnetic resonance diagnostic device
Product Code	90LNH
Class	2
Panel	Radiology
Trade/Proprietary Name:	TRILLIUM Oval V5.1 MRI System
Predicate Device(s):	TRILLIUM Oval MRI System (K142734)

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 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. There is no change in the system composition from the predicate device.

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 TRILLIUM OVAL V5.1 MRI System is only a software update with new features, quality assurance measures was conducted on only the new features which include:

- Multi-b measurement
- Kspace parallel imaging
- T2*Relax MAP
- Vivid Image
- RADAR Enhancement
- DKI
- ASL-Perfusion
- Breast MRS
- Enhanced PC (improvement of Cine PC)
- PBSG for MRH
- Volume RF shimming

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 includes V5.1 software is substantially equivalent to the TRILLIUM OVAL (K142734). See tables below.

The technological characteristics in regards to hardware of the TRILLIUM OVAL V5.1 MRI System and the predicate are listed in Table 2.

Table 2 Comparison: Hardware

ITEM		TRILLIUM OVAL (K142734)	TRILLIUM OVAL	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, 60601-1-1, 60601-1-2, 60601-1-4, 60601-2-33, 62304	No
Magnet and Gantry	Type and Field Strength	Super-conducting magnet, horizontal bore, 3 Tesla	Super-conducting magnet, horizontal bore, 3 Tesla	No
	Resonant Frequency	123.47 MHz	123.47 MHz	No
Gradient System	Gradient Strength	40mT/m	40mT/m	No
	Slew Rate	200 T/m/sec	200 T/m/sec	No
	Rise Time	200μsec to 40mT/m	200μsec to 40mT/m	No
	Audible Noise (MCAN)			
	Ambient	69.7 dBA	62.9 dBA	See table 3
	Lpeak	126.9 dB	133.4 dB	See table 3
	LAeq	118.8 dBA	124.3 dBA	See table 3
RF System	Transmitter channels	4	4	No
	Peak Envelop Power	40 kW	40 kW	No
	Duty Cycle	60% (Gating max), 100ms at full power	60% (Gating max), 100ms at full power	No
	RF receiver channel	16/32	16/32	No

The hardware differences from the TRILLIUM OVAL V5.1 MRI System to the predicate device are analyzed in Table 3.

Table 3 Hardware NSE 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)).21 CFR 807.87(f)).			
Device Modification Summary	Audible Noise (MCAN) is changed (from 118.8 dBA to 124.3 dBA of LAeq), because pulse sequence parameter limitation (BASG (TR), and on GEEPI (IET)) is changed to improve image quality. (see table 7 and 8) Audible Noise (MCAN) measurement method (NEMA MS 4:2010) and risk analysis method performed is same as TRILLIUM OVAL (K142734)			
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 TRILLIUM OVAL (K142734). So, safety and effectively of the device are same as TRILLIUM OVAL (K142734)			

The technological characteristics in regards to RF coils of the TRILIUM OVAL V5.1 MRI System and the predicate are listed in Table 4.

Table 4 Comparison: RF Coils

ITEM		TRILLIUM OVAL (K142734)	TRILLIUM 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 Anterior NV attachment	WIT Anterior NV attachment	No
		WIT Anterior Neck attachment	WIT Anterior Neck attachment	No
		WIT Spine coil 12	WIT Spine coil 12	No
		WIT Spine coil 8	WIT Spine coil 8	No
		WIT Torso coil 12	WIT Torso coil 12	No
		Extremity coil	Extremity coil	No
		Shoulder coil	Shoulder coil	No
		Flexible Extremity coil	Flexible Extremity coil	No
		Foot/Ankle coil	Foot/Ankle coil	No
		Head/Wrist coil	Head/Wrist coil	No
		Breast coil	Breast coil	No
		Micro coil A	Micro coil A	No
		Micro coil B	Micro coil B	No
		WIT Torso coil 8	WIT Torso coil 8	No

The coil differences from the TRILLIUM OVAL V5.1 MRI System to the predicate device are analyzed in Table 5.

Table 5 RF coils NSE 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)). 21 CFR 807.87(f)).			
Device Modification Summary	The performance and technological characteristics of coil is same as TRILLIUM OVAL (K142734)			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
HITACHI Rationale Statement	There is no new intended use. There are no changes in technological characteristics.			

The technological characteristics in regards to changes in functionality of TRILLIUM OVAL V5.1 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 V4.6B to V5.1B	See Table 7
Scan Tasks	None	No
2D Processing Tasks	T2* calculation, Vivid Image	See Table 7
3D Processing Tasks	None	No
Analysis Tasks	DWI analysis (AD, RD, MK, AK, RK, and FAK Maps(*)) are now available on TRILLIUM OVAL V5.1.	See Table 7
SAR and dB/dt Management	SAR management is modified. dB/dt calculation on TRILLIUM OVAL V5.1 is modified.	See Table 7
Maintenance Tasks	None	No
Viewport Tools	None	No
Film, Archive Tools	None	No
Network Tools	None	No
Protocol Enhancements	RF shimming is modified. Multi-b measurement, k-space parallel imaging, T2* Relax Map, RADAR (2DGE, 3D GE, 2D TOF, and 3D TOF), ASL-Perfusion, Enhanced PC(improvement of Cine PC), and Breast MRS are now available on TRILLIUM OVAL V5.1.	See Table 7
Pulse Sequences	2D GEEPI and 2D/3D BASG is changed in sequence parameter, 2D/3D Phase Balanced SARGE (2D PBSG) are now available on TRILLIUM OVAL V5.1.	See Table 7

The functionality differences from the TRILLIUM OVAL V5.1 MRI System to the predicate device are analyzed in Table 7.

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	T2* Calculation (T2*RelaxMap) - Adds the ability to obtain T2* values of tissues as opposed to previous software. Benefits areas such as liver and cartilage imaging. (same function as one equipped on ECHELON OVAL V5.0A K151015) Vivid Image- Enhances image quality in the 2D processing tasks. DWI Analysis- New Maps are added and allow for advanced evaluation of diffusion tensor and diffusion kurtosis imaging. (same function as one equipped on ECHELON OVAL V5.0A K151015) SAR Management- Coil loss coefficient is determined from measured Q values at each subject to improve SAR measurement accuracy. SAR monitor is upgraded to improve precision SAR is limited by IEC 60601-2-33 as same as TRILLIUM OVAL (K142734). dB/dt Calculation- To handle the peripheral nerve stimulation (PNS) threshold level more accurate, Directly determined limits as specified IEC60601-2-33 is used for TRILLIUM OVAL V5.1B system instead of Default values as also specified IEC60601-2-33. We refer 201.12.4.105.1 Direct determination of the limits of the PNS OUTPUT for the measurement. RF Shimming- RF shimming parameter of predefined mode is changed to improve B_1 uniformity. Volume RF shimming mode is added to improve B_1 uniformity. Safety evaluation with using the improved RF shimming function is done with same SAR evaluation method as TRILLIUM OVAL (K142734) that shows safety of the device are same as TRILLIUM OVAL (K142734) 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. (same function as one equipped on ECHELON OVAL V5.0A K151015) k-Space Parallel Imaging - k-Space based parallel imaging. Reduces the occurrence of wrap artifacts. RADAR – 2D/3D GE and 2D/3D TOF pulse sequences can now use RADAR motion correction. ASL-Perfusion - Non-contrast brain perfusion. pASL based gradient echo EPI sequence. Benefits areas such as brain imaging. Enhanced PC (improvement of Cine PC) - Reduces minimum TR/TE and adds RAPID(*) capability. Benefits areas such as artery imaging. Breast MRS - Added single voxel breast spectroscopy (same function as one equipped on ECHELON OVAL V5.0A K151015) 2D GEEPI and 2D/3D BASG -2D GEEPI is changed at minimum inter echo time to improve image quality. 2D/3D BASG is changed at minimum TR to improve image quality. Acoustic noise evaluation is performed as same as TRILLIUM OVAL (K142734). (see table 2) 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, SAR and dB/dt is managed according to IEC60601-2-33, and pulse sequences are controlled according to IEC60601-2-33 as same as TRILLIUM OVAL (K142734).			

Substantial Equivalence

A summary decision was based on analysis of Table 8.

Table 8 Rationale Analysis: TRILLIUM 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	The performance and technological characteristics of coil is same as TRILLIUM OVAL (K142734)
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 TRILLIUM OVAL V5.1 MRI is considered substantially equivalent to the currently marketed predicate device (TRILLIUM OVAL MRI System (K142734)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Summary of Non-Clinical Testing

The revisions to the TRILLIUM OVAL V5.1 MRI System software will have no effect on the standards tests which were conducted on the TRILLIUM OVAL MRI System (K142734) and included in the original submission.

Therefore, TRILLIUM OVAL V5.1 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, quality assurance measures were conducted on the new features of the TRILLIUM V5.1 MRI System, they include:

- **Multi b and DKI**
  Test results from phantom simulations and volunteer studies 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.
- **k-Space Parallel Imaging**
  Test results from phantom simulations and volunteer studies 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.
- **T2* RelaxMap**
  Test results from phantom simulations and volunteer studies 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.
- **Vivid Image**
  Test results from phantom simulations and volunteer studies confirm improvement of overall SNR.
- **RADAR-GE/TOF**
  Test results from phantom simulations and volunteer studies confirm the RADAR measurement feature is functioning with the GE and TOF sequence.
- **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 volunteer studies.
- **Breast MRS**
  Test results from phantom simulations and volunteer studies 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 volunteer studies 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.
- **PBSG**
  Test results from phantom simulations and volunteer studies 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.
- **Volume RF Shimming**
  Test results and volunteer studies confirm that Volume RF shimming improves B1 uniformity.

Summary of Clinical Testing

The modification to the software to include the new features did not require clinical testing.

Conclusions

It is the opinion of Hitachi Medical Systems America, Inc. the TRILLIUM OVAL V5.1 MRI System is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the TRILLIUM OVAL MRI System (K142734).