July 13, 2023

FUJIFILM Healthcare Corporation
% Kotei Aoki
Manager, Regulatory Affairs
FUJIFILM Healthcare Americas Corporation
81 Hartwell Avenue, Suite 300
LEXINGTON MA 02421

Re: K223426
Trade/Device Name: ECHELON Synergy MRI system
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: June 2, 2023
Received: June 2, 2023

Dear Kotei Aoki:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223426

Device Name
ECHELON Synergy MRI system

Indications for Use *(Describe)*

The ECHELON Synergy 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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ECHELON Synergy MRI system
510(k) Summary

K223426

Submitter Information

Submitter:	FUJIFILM Healthcare Corporation 2-1, Shintoyofuta Kashiwa-shi, Chiba, 277-0804 Japan
Contact Person:	Kotei Aoki Manager, Regulatory Affairs
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Telephone number:	765-246-2931
Date:	November 11, 2022

Subject Device Name

Trade/Proprietary Name:	ECHELON Synergy 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 V6.0A MRI system (K172110)
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 Synergy 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 Synergy 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 OVAL V6.0A MRI system. The ECHELON Synergy has been designed to enhance clinical utility as compared to the ECHELON OVAL V6.0A 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.

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 Synergy MRI system software is substantially equivalent to the ECHELON OVAL V6.0A (K172110).

The technological characteristics in regard to hardware of the ECHELON Synergy MRI system and the predicate are listed in Table 1.

Table 1 Comparison: Hardware

ITEM		PREDICATE DEVICE	SUBJECT DEVICE	DIFFERENCE
		ECHELON OVAL V6.0A (K172110)	ECHELON Synergy	
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, MS 14 IEC: 60601-1, 60601-1-2, 60601-2-33, 62304	Yes
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
	Bore dimension	Oval shape with 74cm x 65cm	Circle shape with diameter 70cm	Yes
Gradient System	Gradient Strength	34mT/m	33mT/m	Yes
	Slew Rate	150 T/m/sec	130 T/m/sec	Yes
	Rise Time	227µsec to 34mT/m	254µsec to 33mT/m	Yes
	Audible Noise (MCAN)			
	Ambient	58 dBA	59.9 dBA	Yes
	Lpeak	125 dBA	122.7 dBA	Yes
	Leq	117 dB	116.5 dBA	Yes
RF System	Transmitter channels	2	1	Yes
	Peak Envelop Power	40 kW	18 kW	Yes
	Duty Cycle	100% (Gating max), 12.5% at full power	85% (Gating max), 10% at full power	Yes
	RF receiver channel	16, 32	32	Yes

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

Table 2 Hardware 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	Gantry bore dimension is changed from oval shape with 74cm x 65cm to circle shape with diameter 70cm. Gradient field strength and slew rate, RF system Transmitter channels, Peak Envelop Power and Duty Cycle. Conformity to NEMA MS 14.			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
FUJIFILM Rationale Statement	Modified specifications do not 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. So, safety and effectiveness of the device are same as ECHELON OVAL V6.0A(K172110).			

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

Table 3 Comparison: RF Coils

ITEM		PREDICATE DEVICE	SUBJECT DEVICE	DIFFERENCE
		ECHELON OVAL V6.0A (K172110)	ECHELON Synergy	
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 B	FlexFit Neuro Coil	Yes
		WIT Torso coil WIT Torso coil 12 WIT Torso coil 8	FlexFit Blanket Coil A, FlexFit Blanket Coil B	Yes
		Extremity coil (Knee)	Extremity Coil	No
		WIT Anterior Neck attachment WIT Anterior Neck attachment B	N/A	N/A
		Hand/Wrist coil	Hand/Wrist Coil	No
		WIT Anterior NV attachment	N/A	No
		Breast	Breast Coil	Yes
			Breast Support Kit 2	

ITEM	PREDICATE DEVICE	SUBJECT DEVICE	DIFFERENCE
	ECHELON OVAL V6.0A (K172110)	ECHELON Synergy	
	MP coil 140A, B Micro coil (S) A, B	Micro Coil A, Micro Coil B	Yes
	Shoulder coil Shoulder coil 8	Shoulder Coil	No
	WIT Spine coil 12 WIT Spine coil A WIT Spine coil 8 WIT Spine coil B	Spine Coil	Yes
	Foot/Ankle coil	Foot/Ankle Coil	No
	Flexible Extremity coil (Long Bone)	Flex M coil, Flex S Coil	Yes
	WIT Cardiac coil	N/A	N/A
	PV coil	N/A	N/A

The Extremity Coil, Hand/Wrist Coil, Breast Coil, Micro Coil A, Micro Coil B, Shoulder Coil and Foot/Ankle Coil have an updated interface in order to connect with the ECHELON Synergy MRI system.

The coil differences from the predicate device to the ECHELON Synergy MRI system 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	• FlexFit Neuro Coil is changed from ECHELON OVAL WIT Posterior Head/Neck coil, WIT Anterior Head attachment, WIT Posterior Head/Neck coil B, WIT Anterior Neck attachment and WIT Anterior Neck attachment B. • FlexFit Blanket Coil A and FlexFit Blanket Coil B are changed from ECHELON OVAL WIT Torso coil, WIT Torso coil 12 and WIT Torso coil 8. • Spine Coil is changed from ECHELON OVAL WIT Spine coil 12, WIT Spine coil A, WIT Spine coil 8 and WIT Spine coil B. • Flex M Coil and Flex S Coil are changed from ECHELON OVAL Flexible Extremity coil (Long Bone). • Breast Support Kit 2 is available for Breast Coil as the accessories.			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
FUJIFILM Rationale Statement	Revised coils do not constitute a new intended use. There are no significant changes in technological characteristics. During transmitter coil operation, RF Coils are de-resonated for the safety function by same scheme as ECHELON OVAL(K172110)			

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

Table 5 Comparison: Functionality

ITEM	DIFFERENCES	ANALYSIS
Operating System	Going from Windows 7 to Windows 10 IoT	See Table 6
CPU Platform	Xeon E3-1275 v6 3.8GHz, Xeon Silver 4210 2CPU, Core i5-7440EQ	See Table 6
Application Software	Going from V6.0A to V9.0A	See Table 6
Scan Tasks	Following positioning application of Scan Tasks are added in Auto Pose. -Knee, Shoulder, Spine	See Table 6
2D Processing Tasks	Add the parameter R1 in Parameter Analysis	See Table 6
3D Processing Tasks	Following 3D Processing Tasks are added. - Auto VR - Auto Clip	See Table 6
Analysis Tasks	None	No

ITEM	DIFFERENCES	ANALYSIS
Maintenance Tasks	None	No
Viewport Tools	None	No
Film, Archive Tools	None	No
Network Tools	None	No
Protocol Enhancements	Following protocol enhancement are added. - HiMAR Advanced - Double-IR isoFSE - AutoExam - Auto Table Centering - IP-Recon - IP-Scan - MSDE - Golden Random Sampling - Deep Learning Reconstruction (DLR) - IterativeRAPID - Dynamic slice count per study changes 4096 to 200. - Presaturation pulses changes 8 to 6. - 2D opFSE, 2D opFIR, 2D/3D Prime FSE and 2D/3D Prime FIR are integrated to FSE or FIR in "RADAR" category. - 3D Soft RSSG and 3D Soft RSSG EPI are added in "Soft Sound" category.	See Table 6
Pulse Sequences	Following Pulse sequence are added. - 3D RF Spoiled SARGE (3D Soft RSSG) - 3D RF Spoiled SARGE Echo Planar Imaging (3D Soft RSSG EPI) - 2D T1Map Sequence (2D T1Map) - 2D Phase Sensitive Inversion Recovery (2D PSIR) - 2D IR sequence is integrated to SE using with IR-pulse. - 2D opFSE, 2D opFIR, 2D/3D Prime FSE and 2D/3D Prime FIR are integrated to FSE or FIR. - 2D Time Reversed SARGE (2D TRSG) is not available. - 3D Time Reversed SARGE (3D TRSG) is not available.	See Table 6
Powered by Machine Learning	Following functions are added as powered by Machine Learning - AutoPose (Knee, Shoulder, Spine) - AutoClip -Deep Learning Reconstruction (DLR)	See Table 6

The functionality differences from the predicate device from the ECHELON Synergy MRI System are analyzed in Table 6.

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	Application software is changed in V9.0A. Add the parameter R1 in Parameter Analysis as 2D Processing. Following variation of Scan Tasks are added in Auto Pose: -Knee, Shoulder, Spine Following 3D Processing Tasks are added: - Auto VR - Auto Clip Following protocol enhancement are added: - HiMAR Advanced - Double-IR isoFSE - AutoExam - Auto Table Centering

	- IP-Recon - IP-Scan - MSDE - Golden Random Sampling - Deep Learning Reconstruction (DLR) - IterativeRAPID Following Pulse sequence are added: - 3D RF Spoiled SARGE (3D Soft RSSG) - 3D RF Spoiled SARGE Echo Planar Imaging (3D Soft RSSG EPI) - 2D T1Map Sequence (2D T1Map) - 2D Phase Sensitive Inversion Recovery (2D PSIR)			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
FUJIFILM 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 the same safety limits as ECHELON Oval V6.0 (K172110) Therefore, safety and effectiveness of the device are the same as ECHELON OVAL V6.0A(K172110).			

Substantial Equivalence

A summary decision was based on analysis of Table 7.

Table 7 Rationale Analysis: ECHELON Synergy vs. Predicate

ITEM	Overall Rationale Analysis
Hardware	Modified specifications do not 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. So, safety and effectiveness of the device are same as ECHELON OVAL V6.0A(K172110).
Coils	Revised coils do not constitute a new intended use. There are no significant changes in technological characteristics. During transmitter coil operation, RF Coils are de-resonated for the safety function by same scheme as ECHELON OVAL(K172110)
Functionality	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 the same safety limits as ECHELON Oval V6.0 (K172110) Therefore, safety and effectiveness of the device are the same as ECHELON OVAL V6.0A(K172110).

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 Synergy is considered substantially equivalent to the currently marketed predicate device (ECHELON OVAL V6.0A MRI System (K172110)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Summary of Non-Clinical Testing

The ECHELON Synergy MRI System was evaluated for software and electrical safety according to the following recognized standards:

- ANSI / AAMI 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 4.0:2014, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests.
- IEC 60601-2-33 Edition 3.2 b:2015, medical electrical equipment - part 2-33: particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic.

- IEC 60825-1:2014, safety of laser products – part 1: equipment classification and requirements.
- IEC 62304 Edition 1.1 2015-06, CONSOLIDATED VERSION medical device software - software life cycle processes.

Bench performance testing was conducted on the ECHELON Synergy MRI System according to the following recognized 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 5-2018, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- NEMA MS 8-2016, Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems
- NEMA MS 14-2019, Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems

Summary of Clinical Testing

Clinical image evaluation was performed on the new features and the new receiver coils to ensure that user needs were met. The evaluation confirmed that the new features and the new receiver coils perform as intended for diagnostic use.

Testing Type	Rationale Analysis
Performance Testing - Clinical	Clinical image examples are provided for applicable new features and coils 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.

The validation results of the new features using machine learning (DLR, AutoClip, AutoPose Spine, AutoPose Shoulder, and AutoPose Knee) were described below.

A reader evaluation study was performed by three US certified radiologists on DLR images acquired across a variety of pulse sequences and anatomies. Readers compared pairs of DLR images and conventional images (without DLR) for each case to evaluate image quality of DLR images. The results confirmed that the DLR images were equivalent or better than the conventional images in terms of signal to noise ratio (81 out of 81 cases), sharpness (80 out of 81 cases), lesion conspicuity (45 out of 45 cases with pathology). The radiologists also indicated that the overall image quality of the DLR images was equivalent or better than that of the conventional images in all cases.

The influences of DLR on the motion artifacts were also evaluated by using three image pairs with motion artifacts. The DLR images were rated as better or equivalent image quality in all image pairs and indicated that DLR did not significantly change the appearance of the motion artifacts.

Readers also evaluated the image quality of the DLR images taken with shorter scan time was also performed in 18 cases. Despite of shorter scan time, DLR images were rated as acceptable for routine examinations in all cases.

Additionally, readers compared pairs of high resolution DLR images and low-resolution conventional images. The high resolution DLR images were rated as better or equivalent image quality in all cases.

The information about the data in the above evaluations is shown below.

Data acquisition MRI system	ECHELON OVAL (1.5T MRI, FUJIFILM Healthcare Corporation) ECHELON Smart (1.5T MRI, FUJIFILM Healthcare Corporation) ECHELON Synergy (1.5T MRI, FUJIFILM Healthcare Corporation)
Data acquisition site	FUJIFILM Healthcare Corporation and clinical site
Subject type	Healthy volunteer and patient
Anatomical coverage	Head, Spine, Cardiac, Breast, Abdomen, Pelvis, Shoulder, Wrist, Knee, Ankle
Number of cases	110

The performance comparison between AutoClip and the manual operation was conducted by the certified radiological technologists. The results confirmed that the performance of AutoClip was substantially equivalent to that of manual clipping. The information about the comparison data is shown below.

Data acquisition MRI system	ECHELON Synergy (1.5T MRI, FUJIFILM Healthcare Corporation)
Data acquisition site	FUJIFILM Healthcare Corporation
Subject type	Japanese healthy volunteers
Number of cases	40
Anatomical coverage	Brain
Scan sequence	3D TOF, 3D Soft TOF

The performance tests of AutoPose Spine, Shoulder and Knee, were conducted by the certified radiological technologists. They evaluated that many cases of AutoPose Spine, Shoulder, and Knee were able to reduce the time and number of steps in the slice positioning compared to the manual slice positioning. They also evaluated that the remaining cases of AutoPose Spine, Shoulder, and Knee were able to show the same time and number of steps as the manual slice positioning. The information about the data in the above tests is shown below.

	Spine	Shoulder	Knee
Data acquisition MRI system	ECHELON Synergy (1.5T MRI, FUJIFILM Healthcare Corporation)		
Data acquisition site	FUJIFILM Healthcare Corporation		
Subject type	Japanese healthy volunteers		
Number of cases	146	48	38

Conclusions

The ECHELON Synergy MRI system is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the ECHELON OVAL V6.0A MRI System (K172110).