May 3, 2024

Fujifilm Healthcare Americas Corporation
Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
81 Hartwell Ave Suite 300
Lexington, Massachusetts 02421

Re: K233687
Trade/Device Name: ECHELON Synergy V10.0
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: April 9, 2024
Received: April 9, 2024

Dear Chaitrali Kulkarni:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233687

Device Name

ECHELON Synergy V10.0

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 (TI), 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:
• TI, 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.

K233687

Section 5

510(k) Summary

Submitter Information

Submitter:	FUJIFILM Healthcare Corporation 2-1, Shintoyofuta Kashiwa-shi, Chiba, 277-0804 Japan
Contact:	Ms. Kulkarni Chaitrali
Telephone number:	704-517-4886
Telephone number:	704-517-4886
E-mail:	chaitrali.kulkarni@fujifilm.com
Date:	November 16, 2023

Subject Device Name

Trade/Proprietary Name:	ECHELON Synergy V10.0 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 Synergy MRI system (K223426)
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.

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 Synergy V10.0 MRI System is equivalent to the ECHELON Synergy MRI System (K223426) with following exceptions:

- Camera unit is added for Synergy Vision and Visual StillShot.
- Alternative super-conducting magnet and units related to alternative super-conducting magnet are added.
- Application software is changed to V10.0A.

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 feature. Test data confirmed that new feature perform as intended for diagnostic use.
Performance Testing - Clinical	Clinical image examples are provided for applicable new feature and that we judged to be sufficient to evaluate clinical usability.

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 V10.0 MRI system software is substantially equivalent to the ECHELON Synergy MRI System (K223426). See tables below. The technological characteristics in regard to hardware of the ECHELON Synergy V10.0 MRI system and the predicate are listed in Table 2.

Table 2 Comparison: Hardware

ITEM		PREDICATE DEVICE	SUBJECT DEVICE	DIFFERENCE
		ECHELON SYNERGY MRI SYSTEM (K223426)	ECHELON Synergy V10.0	
System	Standards Met	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	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	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	63.86MHz	63.86MHz	No
	Bore dimension	Circle shape with diameter 70cm	Circle shape with diameter 70cm	No
Gradient System	Gradient Strength	33mT/m	33mT/m	No
	Slew Rate	130 T/m/sec	130 T/m/sec	No
	Rise Time	254µsec to 33mT/m	254µsec to 33mT/m	No
	Audible Noise (MCAN)			
	Ambient	59.9 dBA	59.9 dBA	No
	Lpeak	122.7 dBA	122.7 dBA	No
	Leq	116.5 dBA	116.5 dBA	No
RF System	Transmitter channels	1	1	No
	Peak Envelop Power	18 kW	18 kW	No
	Duty Cycle	85% (Gating max), 10% at full power	85% (Gating max), 10% at full power	No
	RF receiver channel	32	32	No

The hardware differences from the predicate device to the ECHELON Synergy V10.0 MRI System 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	• Camera unit is added for Synergy Vision and Visual StillShot. • Alternative super-conducting magnet and units related to alternative super-conducting magnet are added. The device is changed but there are no significant changes in technology, engineering and performance.			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
FUJIFILM 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 Synergy MRI System (K223426). So, safety and effectively of the device are same as ECHELON Synergy MRI System (K223426).			

The technological characteristics in regards to coils of the ECHELON Synergy V10.0 MRI System and the predicate are listed in Table 4.

Table 4 Comparison: RF Coils

ITEM		PREDICATE DEVICE ECHELON SYNERGY MRI SYSTEM (K223426)	SUBJECT DEVICE ECHELON Synergy V10.0	DIFFERENCE
RF Coils	Transmit Coil	T/R Body	T/R Body	No
	Receiver Coils	FlexFit Neuro Coil	FlexFit Neuro Coil	No
		FlexFit Blanket Coil A, FlexFit Blanket Coil B	FlexFit Blanket Coil A, FlexFit Blanket Coil B	No
		Extremity Coil	Extremity Coil	No
		Hand/Wrist Coil	Hand/Wrist Coil	No
		Breast Coil Breast Support Kit 2	Breast Coil Breast Support Kit 2	No
		Micro Coil A, Micro Coil B	Micro Coil A, Micro Coil B	No
		Shoulder Coil	Shoulder Coil	No
		Spine Coil	Spine Coil	No
		Foot/Ankle Coil	Foot/Ankle Coil	No
		Flex M Coil, Flex S Coil	Flex M Coil, Flex S Coil	No

The coil differences from the predicate device to the ECHELON Synergy MRI system 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	There are no differences from the predicate device.			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
FUJIFILM Rationale Statement	There are no significant changes in technological characteristics. Therefore, safety, intended use and effectively of the RF coils are same as ECHELON Synergy MRI System (K223426).			

The technological characteristics in regard to changes in functionality of the ECHELON Synergy V10.0 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 V9.0A to V10.0A	See Table 7
Scan Tasks	Following function is updated. - Auto Voice Following positioning applications are added. - AutoPose Breast, AutoPose HipJoint Following positioning application is updated. - AutoPose Spine Following function is added. - Series Save	See Table 7
2D Processing Tasks	None	No
3D Processing Tasks	None	No
Analysis Tasks	None	No
Maintenance Tasks	None	No
Viewport Tools	None	No
Film, Archive Tools	None	No
Network Tools	Following Network Tools are added. - AutoProtocol	See Table 7
Protocol Enhancements	Following function is updated. - Delayed Enhancement Imaging - Navi slice positioning - BeamNavi Following variation of Protocol Enhancements are added in Auto Table Centering. - Chest, Breast, General Abdomen, Liver/Kidney, Pelvis, WholeBody Following Protocol Enhancements are added. - Navigated StillShot - Visual StillShot - MROC - IQ Retouch - Exp.RAPID - DWI HD - DLR Clear 2D RADAR sequence is added to the applicable sequence of DLR Rise. 3D sequences and 2D RADAR are added to the applicable sequence of IterativeRAPID. VASC-FSE is modified.	See Table 7
Pulse Sequences	None	No
Monitoring Tools	Following function is added. - Synergy Vision	See Table 7

The functionality differences from the predicate device to the ECHELON Synergy V10.0 MRI System 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	・ Following function is updated in Scan Tasks. - AutoVoice ・ Following positioning applications are added in Scan Tasks. - AutoPose Breast, AutoPose HipJoint

	・ Following positioning application in Scan Tasks is updated. - AutoPose Spine ・ Following function is added. - Series Save ・ Following Network Tool is added. - AutoProtocol ・ Following variation of Protocol Enhancements are added in Auto Table Centering. - Chest, Breast, General Abdomen, Liver/Kidney, Pelvis, WholeBody ・ Following function of Protocol Enhancements is updated. - Delayed Enhancement Imaging - Navi slice positioning - BeamNavi ・ Following Protocol Enhancements are added. - Navigated StillShot - Visual StillShot - MROC - IQ Retouch - Exp.RAPID - DWI HD - DLR Clear ・ Following task is added as “Monitoring Tools”. - Synergy Vision ・ Function name of Deep Learning Reconstruction (DLR) added in ECHELON Synergy MRI System (K223426) is changed DLR Rise. DLR is an abbreviation for Deep Learning Reconstruction. ・ 2D RADAR is added in “DLR Rise” of Protocol Enhancements. ・ 3D sequences and 2D RADAR are added in “IterativeRAPID” of Protocol Enhancements. ・ VASC-FSE of Protocol Enhancements is modified. Application software is changed in V10.0A.

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 Synergy MRI System (K223426). Therefore, safety and effectiveness of the device are the same as ECHELON Synergy MRI System (K223426).			

Substantial Equivalence

A summary decision was based on analysis of Table 8.

Table 8 Rationale Analysis: ECHELON Synergy V10.0 vs. Predicate

ITEM	Overall Rationale Analysis
Hardware	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 Synergy MRI System (K223426). So, safety and effectively of the device are same as ECHELON Synergy MRI System (K223426).
Coils	There are no differences regarding receiver coils.
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 Synergy MRI System (K223426). Therefore, safety and effectiveness of the device are the same as ECHELON Synergy MRI System (K223426).

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 V10.0 is considered substantially equivalent to the currently marketed predicate device (ECHELON Synergy MRI System (K223426)) 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 subjected to the following laboratory testing.

- 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 60601-2-33 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 62304 Edition 1.1 2015-06, CONSOLIDATED VERSION medical device software - software life cycle processes.
- 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.

The revisions to the ECHELON Synergy V10.0 MRI System will have no effect on the standards tests, which were conducted on the ECHELON Synergy MRI System (K223426) and included in the original submission.

Therefore, ECHELON Synergy V10.0 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 5-2018, 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
- IEC 60825-1:2014, safety of laser products – part 1: equipment classification and requirements.

Summary of Clinical Testing

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

The validation results of the new features using machine learning (DLR Clear and AutoPose) were described below.

Performance tests of DLR Clear were conducted by using cylindrical phantom and ACR phantom in terms of truncation artifact reduction, improvement of image sharpness, and improvement of spatial resolution with the sampling patterns of 2D Cartesian, 2D Radial, 3D Rectangular, and 3D Elliptic. Using metrics of Total Validation, Relative Edge Sharpness, and FWHM (Full Width at Half Minimum) of the line-profile of the holes in the ACR phantom, the phantom testing demonstrated that DLR Clear could reduce the truncation artifact in the image, improve image sharpness, and improve the spatial resolution of image.
In addition, three US board certified radiologists reviewed the image quality with DLR Clear in terms of the truncation artifact reduction, image sharpness, spatial resolution of image. The

images reconstructed with either the conventional method or DLR Clear were randomized, blinded to the reviewers, and compared by the reviewers in terms of image quality metrics (truncation artifact reduction, image sharpness, lesion conspicuity, and overall image quality) using 3-point scale. All images used for this comparison were also evaluated by the reviewers in terms of clinical acceptability. The 53 unique subjects (patients and volunteers) from U.S. and Japan (Male: 33, Female: 20, Age: 9 - 92 years, BMI:18.9 – 50.5) were scanned in the anatomical regions from brain to ankle in order to provide the test datasets separately from the training and validation datasets using FUJIFILM 1.5T MRI Scanners (ECHELON Smart, ECHELON OVAL, and ECHELON Synergy). The total of 169 images in multiple orientations (axial, sagittal and coronal), multiple dimensions (2D and 3D), and various contrast weightings (T1-/T2-/T2*-/PD-weighted image with/without Fat saturation, FLAIR, DWI, MRA, MRCP, STIR, and Cine) were obtained for the test dataset by pulse sequences of SE, GE, FSE, FIR, BASG, RSSG, EPI, TOF, and PC. The review results indicated that the truncation artifact reduction, image sharpness, and overall image quality in the images with DLR Clear were superior to those in the conventional images with statistically significant difference ($p<0.05$). The review results also indicated that the lesion conspicuity in the images with DLR Clear was superior or equivalent to that in the conventional images. All of the images with DLR Clear were evaluated as clinically acceptable by the reviewers. The comparison of the overall image quality between the high-resolution images with DLR Clear and the low-resolution images without DLR Clear was also performed by the radiologists. The pairs of the high-resolution images with DLR Clear and the low-resolution images without DLR Clear, reconstructed from the same acquired data, were prepared from the test dataset. All images used for this comparison were evaluated by the radiologists in terms of clinical acceptability. The review results indicated that the overall image quality in the high-resolution images with DLR Clear were superior to that in the low-resolution images without DLR Clear with statistically significant difference and were clinically acceptable. In conclusion, the phantom testing and the clinical Image testing demonstrated that DLR Clear could reduce the truncation artifact in the image, improve image sharpness, and generate higher spatial resolution images from lower resolution images.

The performance tests of AutoPose Spine, Breast and HipJoint, were conducted by the certified radiological technologists. They evaluated that almost cases in AutoPose Spine, Breast, and HipJoint, 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, Breast, and HipJoint were able to show the same time and number of steps as the manual slice positioning. The information on the data in the above evaluations is shown below.

	Spine	Breast	HipJoint
Data acquisition site	FUJIFILM Healthcare Corporation and clinical site		
Subject type	Healthy volunteer and patients		
Number of cases	177	66	65

As a result of the analysis:

Testing Type	Rationale Analysis
Performance Testing – Clinical	Clinical image examples are provided for applicable new feature and that we judged to be sufficient to evaluate clinical usability.

Conclusions

The ECHELON Synergy V10.0 MRI system is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the ECHELON Synergy MRI System (K223426).