August 13, 2024

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

Re: K241429
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: May 21, 2024
Received: May 21, 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)*

K241429

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 (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.

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510(k) Summary

Submitter Information

Submitter:	FUJIFILM Healthcare Corporation 2-1, Shintoyofuta Kashiwa-shi, Chiba, 277-0804 Japan
Contact:	David Loeser Regulatory Affairs Specialist
Telephone number:	703-472-9452
Telephone number:	HCUSRegulatoryAffairs@fujifilm.com
Data:	May 15, 2024

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 Synergy V10.0 (K233687)
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 MRI System is equivalent to the ECHELON Synergy V10.0 (K233687) with following exceptions:

- Breast Coil 17 is added.

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 MRI System is substantially equivalent to the ECHELON Synergy V10.0 (K233687). See tables below.
Te technological characteristics in regard to software of the ECHELON Synergy MRI System and the predicate are listed in Table 2.

Table 2 Comparison: Hardware

ITEM		PREDICATE DEVICE	SUBJECT DEVICE	DIFFERENCE
		ECHELON Synergy V10.0 (K233687)	ECHELON Synergy MRI System	
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 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	The new receiver coil named Breast coil 17 is added to ECHELON Synergy MRI system. 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	Added coil 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 V10.0 (K233687). So, safety and effectively of the device are same as ECHELON Synergy V10.0 (K233687).			

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

Table 4 Comparison: RF Coils

ITEM		PREDICATE DEVICE	SUBJECT DEVICE	DIFFERENCE
		ECHELON Synergy V10.0 (K233687)	ECHELON Synergy MRI System	
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 Breast Coil 17 Breast Support Holder	Yes
		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	Breast coil 17 is added to ECHELON synergy MRI system.			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐ Technology	☐ Performance
	☐ Engineering	☐ Materials	☐ Others	☑ None (See rationale statement)
FUJIFILM Rationale Statement	Added coil doesn't constitute a new intended use. There are no significant changes in technological characteristics. Therefore, safety, intended use and effectively of the RF coils are same as ECHELON Synergy V10.0 (K233687).			

The technological characteristics in regard to changes in functionality of the ECHELON Synergy 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	None	No
Scan Tasks	None	No
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	None	No
Protocol Enhancements	None	No
Pulse Sequences	None	No
Monitoring Tools	None	No

The functionality differences from the predicate device to the ECHELON Synergy 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	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. For safety, pulse sequences are controlled according to the same safety limits as ECHELON Synergy V10.0 (K233687). Therefore, safety and effectiveness of the device are the same as ECHELON Synergy V10.0 (K233687).			

Substantial Equivalence

A summary decision was based on analysis of Table 8.

Table 8 Rationale Analysis: ECHELON Synergy MRI System vs. Predicate

ITEM	Overall Rationale Analysis
Hardware	There are no differences regarding hardware units.
Coils	Added coil 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 V10.0 (K233687). So, safety and effectively of the device are same as ECHELON Synergy V10.0 (K233687).
Functionality	There are no differences regarding software functionality.

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 MRI System is considered substantially equivalent to the currently marketed predicate device (ECHELON Synergy V10.0 (K233687)) 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 4.1:2020-09, CONSOLIDATED VERSION 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 MRI System will have no effect on the standards tests, which were conducted on the ECHELON Synergy V10.0 (K233687) and included in the original submission.

Therefore, ECHELON Synergy 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 Standards Publication MS 14-2019, Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems
- IEC 60825-1 Edition 2.0 2007-03, Safety of laser products – Part 1 : Equipment classification and requirements [including : Technical Corrigendum 1 (2008) interpretation Sheet 1 (2007) Interpretaion Sheet 2 (2007)]

Summary of Clinical Testing

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

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. In addition, a radiologist validated that the clinical images have acceptable image quality for clinical use.

Conclusions

The ECHELON Synergy MRI System is substantially equivalent with respect to hardware, software, safety, effectiveness, and functionality to the ECHELON Synergy V10.0 (K233687).