May 10, 2024

FUJIFILM Healthcare Corporation
Kotei Aoki
Manager, Regulatory Affairs
81 Hartwell Avenue, Suite 300
Lexington, Massachusetts 02421

Re: K233629
Trade/Device Name: APERTO Lucent MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: April 2, 2024
Received: April 11, 2024

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 (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)*

K233629

Device Name

APERTO Lucent MRI System

Indications for Use *(Describe)*

The APERTO Lucent 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

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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Submitter Information

Submitter:	FUJIFILM Healthcare Corporation 2-1, Shintoyofuta Kashiwa-Shi, Chiba, 277-0804 Japan
Contact:	Kotei Aoki
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Date:	November 10, 2023

Subject Device Name

Trade/Proprietary Name:	APERTO Lucent 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):	AIRIS Elite V4.9 MRI system (K032232)
Regulation Number:	21 CFR 892.1000
Regulation Name:	System, Nuclear Magnetic Resonance Imaging
Product Code	LNH
Class	2
Panel	Radiology

Device Intended Use

The APERTO Lucent 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

Device Description

Function

The APERTO Lucent is a modification of the AIRIS Elite MRI System. The APERTO Lucent has been revised to increase the clinical utility as compared to the AIRIS Elite Magnetic Resonance imaging system.

.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.

Performance Evaluation

The APERTO Lucent MRI System is equivalent to the AIRIS Elite V4.9 (K032232) with following exceptions:

- Field strength is changed from 0.3T to 0.4T.
- Gradient field strength is change from 21mT/m to 22mT/m.
- Patient table
- Software operating system is changed to Windows 10 IoT from UNIX.

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

Device Technological Characteristics

The control and image processing hardware and the base elements of the system software are identical to the predicate device. The APERTO Lucent MRI system software is substantially equivalent to the AIRIS Elite V4.9A (K0323232). See tables below.
The technological characteristics in regard to hardware of the APERTO Lucent MRI system and the predicate are listed in Table 2.

Table 2 Comparison: Hardware

ITEM		PREDICATE DEVICE	SUBJECT DEVICE	DIFFERENCE
		AIRIS ELITE(K032232)	APERTO LUCENT	
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	0.3T Permanent magnet	0.4T Permanent magnet	Yes
	Resonant Frequency	12.7 MHz	16.18MHz	Yes
Gradient System	Gradient Strength	21mT/m	22mT/m	Yes
	Slew Rate	55 T/m/sec	55 T/m/sec	No
	Rise Time	380μsec to 21mT/m	400μsec to 22mT/m	Yes
	Audible Noise (MCAN)			
	Ambient	-	47.4 dBA	Yes
	Lpeak	-	104.4 dB	Yes
	Leq	< 104dBA	91.4 dBA	Yes
RF System	Transmitter channels	4	4	No
	Peak Envelop Power	5 kW	5 kW	No
	Duty Cycle	15% square wave	10% square wave	Yes
	RF receiver channel	2	2	No

The hardware differences from the predicate device to the APERTO Lucent 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	• Field strength is changed from 0.3T to 0.4T. • Resonant Frequency is changed from 12.7MHz to 16.18MHz. • Gradient field strength is changed from 21mT/m to 22mT/m. • Audible Noise is re-measured. • Duty Cycle is changed from 15% to 10%.			
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 AIRIS Elite. So, safety and effectively of the device are same as AIRIS Elite(K032232).			

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

Table 4 Comparison: RF Coils

ITEM		PREDICATE DEVICE	SUBJECT DEVICE	DIFFERENCE
		AIRIS ELITE(K032232)	APERTO LUCENT	
RF Coils	Receiver Coils	Open MA head coil	QD Head coil R	Yes
		MA Flexible Body coil (Medium)	N/A	N/A
		MA Flexible Body coil (Large)	QD Flexible Body coil N (L)	Yes
		MA Flexible Body coil (Extra Large)	N/A	N/A
		Medium extremity(neck) coil	Joint coil(M)	Yes
		Large extremity(neck) coil	Joint coil(L)	Yes
		MA Knee coil	QD Knee coil R	Yes
		TMJ coil	N/A	N/A
		MA Wrist coil	QD Wrist coil	Yes
		N/A	C-Spine coil	N/A
		N/A	QD Head coil (L)	N/A
		N/A	MA Shoulder coil	N/A

The coil differences from the predicate device to the APERTO Lucent 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	• Head Coil is changed from Open MA head coil to QD Head coil R. • Flexible Body coil is changed from MA Flexible Body coil(Large) to QD Flexible Body coil N(L). • Joint coil is changed Medium extremity(neck) coil to Joint coil(M). • Joint coil is changed Large extremity(neck) coil to Joint coil(L). • Knee coil is changed MA Knee coil to QD Knee coil R. • Wrist coil is changed MA Wrist coil to QD Wrist coil. • Deleted the following coils. - MA Flexible Body coil (Medium) - MA Flexible Body coil (Extra Large) - TMJ coil • Added the following coils. - C-Spine coil - QD Head coil (L) - MA Shoulder coil			
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 AIRIS Elite(K032232)			

The technological characteristics in regard to changes in functionality of the APERTO Lucent MRI System as compared to the predicate are listed in Table 6.

Table 6 Comparison: Functionality

ITEM	DIFFERENCES	ANALYSIS
Operating System	Going from UNIX to Windows 10 IoT	See Table 7
CPU Platform	Xeon E3-1275 v6 3.8GHz	See Table 7
Application Software	Going from V4.9 to V7.1E	See Table 7
Scan Tasks	Following Scan Tasks are added. - RAPID is not available. - Interactive Scan Control - Radial Stack - Auto Pose (Brain)	See Table 7
2D Processing Tasks	Following 2D Processing Tasks are added. - Uniformity is not available. - Image division - Image Stitching Add the parameter R2, R1 in Parameter Analysis	See Table 7
3D Processing Tasks	Following 3D Processing Tasks are added. - Volume Rendering	See Table 7
Analysis Tasks	None	No
Maintenance Tasks	None	No
Viewport Tools	Following Viewport Tools are added. - SIR Map	See Table 7
Film, Archive Tools	Following Film Tools are added. - Auto filming is not available.	See Table 7
Network Tools	Following Network Tool are added - DICOM Modality Performed Procedure Step - DICOM Storage commitment	See Table 7
Protocol Enhancements	Following protocol enhancement are added. - Multi-Slice/Multi-phase Cardiac Gating Navigator Echo Functions - Time Resolved Angiography - Fluoro Triggered Angiography - Black blood imaging - Arrhythmia rejection - 3DGEIR - Blood Sensitive Imaging (BSI) - RADAR (2D FSE, 3D FSE, 2D FIR, 3D FIR, 2D SE, 2D GE, 3D GE) - IP-Recon - IP-Scan - VASC-ASL	See Table 7
Pulse Sequences	Following Pulse sequence are added. - 2D Inversion Recovery(2D IR) is not available. (*1) - 2D Time Reversed SARGE (2D TRSG) is not available. - 3D Time Reversed SARGE (3D TRSG) is not available. - 2D Fast Spin Echo (2D primeFSE) - 3D Fast Spin Echo (3D primeFSE) - 2D Fast Inversion Recovery (2D primeFIR) - 3D Fast Inversion Recovery (3D primeFIR) - 2D RADAR DW Fast Spin Echo (2D DW FSE) - 2D Fast Spin Echo Fat Water Separation (2D FATSEPFSE)	See Table 7
Powered by Machine Learning	None	No

The functionality differences from the predicate device from the APERTO Lucent 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	Application software is changed in V7.1E. Following Scan Tasks are added. - RAPID is not available. - Interactive Scan Control - Radial Stack - Auto Pose (Brain) Following 2D Processing Tasks are added. - Uniformity is not available. - Image division - Image Stitching Add the parameter R2, R1 in Parameter Analysis as 2D Processing. Following 3D Processing Tasks are added. - Volume Rendering Following Viewport Tools are added. - SIR Map Following Film Tools are added. - Auto filming is not available. Following Network Tools are added. - DICOM Modality Performed Procedure Step - DICOM Storage commitment Following protocol enhancement are added. - Multi-Slice/Multi-phase Cardiac Gating Navigator Echo Functions - Time Resolved Angiography - Fluoro Triggered Angiography - Black blood imaging - Arrhythmia rejection - 3DGEIR - Blood Sensitive Imaging (BSI) - RADAR (2D FSE, 3D FSE, 2D FIR, 3D FIR, 2D SE, 2D GE, 3D GE) - IP-Recon - IP-Scan - VASC-ASL Following Pulse sequence are added. - 2D Inversion Recovery(2D IR) is not available. (*1) - 2D Time Reversed SARGE (2D TRSG) is not available. - 3D Time Reversed SARGE (3D TRSG) is not available. - 2D Fast Spin Echo (2D primeFSE) - 3D Fast Spin Echo (3D primeFSE) - 2D Fast Inversion Recovery (2D primeFIR) - 3D Fast Inversion Recovery (3D primeFIR) - 2D RADAR DW Fast Spin Echo (2D DW FSE) - 2D Fast Spin Echo Fat Water Separation (2D FATSEPFSE) *1 2D IR sequence is integrated to SE using with IR-pulse.
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. So, safety and effectively of the device are same as AIRIS Elite (K032232).

Substantial Equivalence

A summary decision was based on analysis of Table 8.

Table 8 Rationale Analysis: APERTO Lucent 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 AIRIS Elite V4.9A(K032232). So, safety and effectively of the device are same as AIRIS Elite V4.9A(K032232).
Coils	Revised coils do not constitute a new intended use. There are no significant changes in technological characteristics.
Functionality	Additional functions do not constitute a new intended use. There are no significant changes in technological characteristics. So, safety and effectivity of the device are equivalent to AIRIS Elite (K032232).

Therefore, based on a thorough analysis and comparison of the functions, scientific concepts, physical and performance characteristics, performance comparison and technological characteristics, the proposed APERTO Lucent is considered substantially equivalent to the currently marketed predicate device (AIRIS Elite V4.9A MRI System (K032232)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Summary of Non-Clinical Testing

The APERTO Lucent MRI System was subjected to the following laboratory testing.

- IEC60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM:2012, Medical electrical equipment - part 1: general requirements for basic safety and essential performance
- 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.
- 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 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 62464-1 Edition 2.0 2018-12 Magnetic resonance equipment for medical imaging Part1: Determination of many essential image quality

Summary of Clinical Testing

Clinical images were collected and analyzed, to ensure that images from the new feature and three new RF coils 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 three new RF 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.

Conclusions

It is the opinion of FUJIFILM, the APERTO Lucent MRI system is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the AIRIS Elite V4.9A MRI System (K032332).