April 12, 2024

Fujifilm Healthcare Corporation
Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
2-1, Shintoyofuta
Kashiwa-shi, Chiba 277-0804
Japan

Re: K240571
Trade/Device Name: OASIS MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: February 29, 2024
Received: February 29, 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)*

K240571

Device Name

OASIS MRI System

Indications for Use *(Describe)*

The OASIS MRI System is an imaging device, and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

Anatomical Region: Head, Body, Spine, Extremities
Nucleus excited: Proton
Diagnostic uses: T1, T2, proton density weighted imaging
Diffusion weighted imaging
MR Angiography
Image processing
Spectroscopy
Whole Body

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K240571

Submitter Information

Submitter:	FUJIFILM Healthcare Corporation 2-1, Shintoyofuta Kashiwa-Shi, Chiba JP 277-0804
Contact:	David Loeser Regulatory Affairs Specialist
Telephone number:	703-472-9452
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Date:	February 29, 2024

Subject Device Name

Trade/Proprietary Name:	OASIS 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):	OASIS MRI System (K211406)
Regulation Number:	21 CFR 892.1000
Regulation Name:	System, Nuclear Magnetic Resonance Imaging
Product Code	LNH
Class	2
Panel	Radiology

Reference Device Name

Reference 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 OASIS MRI System is an imaging device, and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

Anatomical Region: Head, Body, Spine, Extremities

Nucleus excited: Proton

Diagnostic uses:

- T1, T2, proton density weighted imaging
- Diffusion weighted imaging
- MR Angiography
- Image processing
- Spectroscopy
- Whole Body

Device Description

Function

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The OASIS MRI System is a Magnetic Resonance Imaging System that utilizes a 1.2 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 OASIS MRI System is equivalent to the OASIS MRI System (K211406) with following exceptions:

- Application software is changed to V9.0E.

- DLR Rise, IterativeRAPID, and DIR are available.
- IP-Recon and IP-Scan are modified.

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 OASIS MRI System software is substantially equivalent to the OASIS MRI System (K211406). See tables below.
The technological characteristics in regard to hardware of the OASIS MRI system and the predicate are listed in Table 2.

Table 2 Comparison: Hardware

ITEM		PREDICATE DEVICE	SUBJECT DEVICE	DIFFERENCE
		OASIS MRI System (K211406)	OASIS MRI System	
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, IEC: 60601-1, 60601-1-2, 60601-2-33, 62304	No
Magnet and Gantry	Type and Field Strength	Super-conducting open magnet, 1.2 Tesla	Super-conducting open magnet, 1.2 Tesla	No
	Resonant Frequency	49.39MHz ± 98 kHz	49.39MHz ± 98 kHz	No
Gradient System	Gradient Strength	33mT/m	33mT/m	No
	Slew Rate	100 T/m/sec	100 T/m/sec	No
	Rise Time	300µsec to 30mT/m	300µsec to 30mT/m	No
	Audible Noise (MCAN)			
	Ambient	63 dBA	63 dBA	No
	Lpeak	126.3 dBA	126.3 dBA	No
	Leq	119 dBA	119 dBA	No
RF System	Transmitter channels	2	2	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	16	16	No
System Control Unit	Unit Type	IRCP	IRCP	No
Console	Storage type	HDD	SSD	Yes
	Memory capacity	16GB	32GB	Yes
IRCP Unit	Storage	HDD	SSD	Yes
	Memory capacity	16GB	32GB	Yes

The hardware differences from the predicate device to the OASIS 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 storage type of the console is changed from HDD to SSD, and the memory capacity is changed from 16GB to 32GB. · The storage type of the IRCP unit is changed from HDD to SSD, and the memory capacity is changed from 32GB to 64GB.			
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 OASIS MRI System.

The technological characteristics in regard to coils of the OASIS MRI System and the predicate are listed in Table 4.

Table 4 Comparison: RF Coils

ITEM		PREDICATE DEVICE OASIS MRI System (K211406)	SUBJECT DEVICE OASIS MRI System	DIFFERENCE
RF Coils	Transmit Coil	T/R Body	T/R Body	No
	Receiver Coils	Extremity Coil	Extremity Coil	No
		Wrist Coil	Wrist Coil	No
		Shoulder Coil	Shoulder Coil	No
		Multipurpose Coil	Multipurpose Coil	No
		Micro Coil	Micro Coil	No
		Foot/Ankle Coil	Foot/Ankle Coil	No
		Breast Coil	Breast Coil	No
		Breast Support Kit 2	Breast Support Kit 2	No
		Large Flex Coil	Large Flex Coil	No
		Extra Large Flex Coil	Extra Large Flex Coil	No
		WIT Spine Coil (Rev.A)	WIT Spine Coil (Rev.A)	No
		WIT Head/Neck Coil	WIT Head/Neck Coil	No
		WIT Head Attachment	WIT Head Attachment	No
		WIT Head/Neck Attachment	WIT Head/Neck Attachment	No
		WIT Neck Attachment	WIT Neck Attachment	No
		WIT Torso Coil A	WIT Torso Coil A	No
		WIT Torso Coil B	WIT Torso Coil B	No

The coil differences from the predicate device to the OASIS 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 OASIS MRI System (K211406).			

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

Table 6 Comparison: Functionality

ITEM	DIFFERENCES	ANALYSIS
Operating System	None	None
CPU Platform	None	None
Application Software	Going from V7.2E to V9.0E	See Table 7
Scan Tasks	None	None
2D Processing Tasks	None	None
3D Processing Tasks	None	None
Analysis Tasks	None	None
Maintenance Tasks	None	None
Viewport Tools	None	None
Film, Archive Tools	None	None
Network Tools	None	None
Imaging Functions	Following functions are added. - DLR Rise - IterativeRAPID - DIR (Double-IR isoFSE) Following functions are modified. - IP-Recon - IP-Scan	See Table 7
Pulse Sequences	None	None

The functionality differences from the predicate device to the OASIS 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 to V9.0E. • DLR Rise, IterativeRAPID, and DIR are added. The AI algorithm and learning condition of DLR Rise in the subject device are the same as those of DLR Rise in the reference device (K223426). The pulse sequence and architecture of DIR function of the subject device are completely the same as those of DIR function of the reference device (K223426). The algorithm and parameter of IterativeRAPID of the subject device are completely the same as IterativeRAPID in the reference device (K223426). • IP-Recon and IP-Scan are modified.			
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 OASIS MRI System (K211406).			

Substantial Equivalence

A summary decision was based on analysis of Table 8.

Table 8 Rationale Analysis: OASIS MRI System 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 OASIS MRI System (K211406). So, safety and effectively of the device are same as OASIS MRI System (K211406).
Coils	There are no significant changes in technological characteristics. Therefore, safety, intended use and effectively of the RF coils are same as OASIS MRI System (K211406).
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 OASIS MRI System (K211406)

Therefore, based on a thorough analysis and comparison of the functions, scientific concepts, physical and performance characteristics, performance comparison and technological characteristics, the proposed OASIS MRI System is considered substantially equivalent to the currently marketed predicate device (OASIS MRI System (K211406)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Summary of Non-Clinical Testing

The OASIS 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.

The revisions to the OASIS MRI System will have no effect on the standards tests, which were conducted on the OASIS MRI System (K211406) and included in the original submission.

Therefore, OASIS 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
- 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.

- 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) Interpretation Sheet 2 (2007)]

Summary of Clinical Testing

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

DLR Rise: Three US board certified radiologists, who had at least 5 years' experience since residency, reviewed the image quality with DLR Rise. The images reconstructed with either the conventional method or DLR Rise were randomized, blinded to the reviewers, and compared by the reviewers in terms of image quality metrics (SNR, sharpness, lesion conspicuity, and overall image quality). All images used for this comparison were also evaluated by the reviewers in terms of clinical acceptability. After each radiologist reviews, the combination of three radiologists' answers was obtained by majority decision, and the combined answers were used for this evaluation. The 71 unique subjects (patients and volunteers) from U.S. and Japan (Male: 38, Female: 33, Age: 21 - 91 years, BMI:15.2 – 55.1) 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 1.2T MRI Scanners (OASIS and OASIS Velocity). The total of 124 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 SNR, sharpness, lesion conspicuity, and overall image quality in the images with DLR Rise were superior to those in the conventional images with statistically significant difference ($p<0.05$). The review results also indicated that all of the images with DLR Rise were rated as better or equivalent image quality compared to the images without DLR Rise. All of the images with DLR Rise were also evaluated as clinically acceptable by the reviewers. The influences of DLR Rise on images with artifacts were also evaluated by the reviewers in terms of image quality metrics (SNR, sharpness, lesion conspicuity, and overall image quality). The images with DLR Rise were rated as better or equivalent image quality in all images with artifacts. This result indicated that DLR Rise did not degrade the quality of images with artifacts.

In conclusion, the clinical Image testing demonstrated that DLR Rise improved SNR and image quality of clinical images compared to the predicate device and the images with DLR Rise were clinically acceptable.

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

It is the opinion of FUJIFILM, the OASIS MRI System is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the OASIS MRI System (K211406).