Hitachi Healthcare Americas
℅ Aaron Pierce
Director, RA/QA
1959 Summit Commerce Park
TWINSBURG OH 44087

October 21, 2020

Re: K202030
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: October 12, 2020
Received: October 14, 2020

Dear Aaron Pierce:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202030

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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Section 5
510(k) Statement or Summary

Submitter Information

Submitter:	Hitachi Healthcare Americas 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
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Date:	October 12, 2020

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	II
Panel	Radiology

Predicate Device Name

Predicate Device(s):	OASIS MRI System (K192851)
Regulation Number:	21 CFR 892.1000
Regulation Name:	System, Nuclear Magnetic Resonance Imaging
Product Code	LNH
Class	II
Panel	Radiology

Indications for 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

The OASIS 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. In addition the OASIS MR system has the Function of measuring spectroscopy.

Performance Evaluation

The OASIS V7.0D MRI System is equivalent to the OASIS MRI (K192851) with the following exceptions:

- Control unit changed from RFIP unit to IRCP unit
- RF receiver channel is expanded from eight (8) to sixteen (16)
- WIT Spine Coil is added to product specification
- RAPID Body Coil and RAPID C-spine Coil are deleted from product specification.
- Operating System is changed from Windows 7 to Windows 10 IoT
- CPU performance is improved from Xeon 3.5 GHz to Xeon 3.8 GHz.
- Application software is revised to V7.0D.

A rationale analysis was then conducted and the results are contained below.

Testing Type	Rationale Analysis
Performance Testing - Bench	Performance bench testing was conducted on the applicable new features. Test data confirmed that each new feature perform as intended for diagnostic use.
Performance Testing - Clinical	Clinical image examples are provided for each applicable new feature and or coil 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 w/V6.0F software is substantially equivalent to the OASIS (K093044). See tables below.

The technological characteristics in regards to hardware of the OASIS MRI system w/V6.0F and the predicate are listed below:

ITEM		OASIS (K192851)	OASIS	DIFFERENCE
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 ±100 kHz	49.39MHz ±98 kHz	See Table 1
Gradient System	Gradient Strength	33mT/m	33mT/m	No
	Slew Rate	100 T/m/sec	100 T/m/sec	No
	Rise Time	300μsec to30mT/m	300μsec to30mT/m	No
	Audible Noise (MCAN)			
	Ambient	63.0 dBA	63.0 dBA	No
	Lpeak	126.3dB	126.3dB	No
	Leq	119dBA	119dBA	No
RF System	Transmitter channels	2	2	No
	Peak Envelop Power	18 kW	18 kW	No
	Duty Cycle	60% (Gating max), 10% at full power	85% (Gating max), 10% at full power	See Table 1
	RF receiver channel	8	16	See Table 1
System Control Unit	Unit Type	RFIP	IRCP	See Table 1

The hardware differences from the OASIS MRI system to the predicate device are analyzed in the table below:

Table 1 Hardware NSE 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	• Reference range of "Resonant Frequency" changed, but this is a correction of miscalculation according to the conversion from field strength (Tesla) to frequency (Hz). No change to the magnet itself. • Maximum duty of RF amplifier is changed from 60% to 85%. The device is changed but there is no performance change as a system because the RF output is controlled by the same sequence specification as OASIS (K192851). • RF receiver channel is expanded from eight (8) to sixteen (16). • System control unit is changed from RFIP unit to IRCP unit. The device is changed but there is no change in performance except for the number of receiver channels.			
Significant Changes	☐Manufacturing Process	☐Labeling	☐Technology	☐Performance
	☐Engineering	☐Materials	☐Others	☑ None (See rationale statement)
HITACHI 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 (K192851). So, safety and effectively of the device are same as OASIS (K192851).			

The technological characteristics in regards to coils of the OASIS MRI system and the predicate are listed in the table below:

ITEM		OASIS (K192851)	OASIS	DIFFERENCE
RF Coils	Transmit Coil	T/R Body	T/R Body	No
	Receiver Coils	Rapid Head	Head Coil	See Table 2
		Rapid Body	-	See Table 2
		Rapid Knee	Extremity Coil	See Table 2
		Rapid C-spine	-	See Table 2
		Rapid Wrist	Wrist Coil	See Table 2
		Rapid Shoulder	Shoulder Coil	See Table 2
		Large Joint	Multipurpose Coil	See Table 2
		Micro coil (S)	Micro Coil	See Table 2
		Foot/Ankle coil	Foot/Ankle Coil	See Table 2
			Breast Coil	See Table 2
			Large Flex Coil	See Table 2
			Extra Large Flex Coil	See Table 2
			WIT Spine Coil	See Table 2

The coil differences from the OASIS MRI system to the predicate device are analyzed in the table below:

Table 2 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	• WIT Spine Coil is added as new 16 channel receiver coil. • RAPID Body Coil and RAPID C-spine Coil are deleted. • Head Coil, Extremity Coil, Wrist Coil, Shoulder Coil, Multipurpose Coil, Micro Coil and Foot/Ankle Coil are same coils as in the lineup of OASIS (K192851), but its name and cable connector is changed to match the interface of the new system. The performance and technological characteristics of the coils are the same as OASIS (K192851). The methodology to check the signal-to-noise performance is changed from NEMA MS 1 method 1 to NEMA MS 1 method 4. • Breast Coil, Large Flex Coil and Extra Large Flex Coil are same coils as approved as K073310 and K080062, but its name and cable connector is changed to match the interface of the new system. The performance and technological characteristics of the coils are the same as K073310 and K080062. The methodology to check the signal-to-noise performance is changed from NEMA MS 1 method 1 to NEMA MS 1 method 4.			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐Technology	☐Performance
	☐Engineering	☐Materials	☐Others	☑None (See rationale statement)
HITACHI Rationale Statement	Additional or modified coils did not constitute a new intended use. There are no significant changes in technological characteristics. During transmitter coil operation, RF Coils are de-resonated by same scheme as OASIS (K192851). WIT Spine Coil is a new receiver coil has the capability of sixteen (16) channels. This is an expansion of maximum number of receiver channel compared to OASIS (K192851).			

The technological characteristics in regards to changes in functionality of the OASIS MRI System as compared to the predicate are listed in the table below:

ITEM	DIFFERENCES	ANALYSIS
Operating System	Going from Windows 7 and 10 IoT to Windows 10 IoT.	See Table 3
CPU Platform	Going from Xeon 3.5 GHz to Xeon 3.8 GHz.	See Table 3
Application Software	Going from V6.0F to V7.0D.	See Table 3
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	Maximum available Presaturation pulse number is changed to 6.	See Table 3
Pulse Sequences	2D IR, 2D TRSG and 3D TRSG sequences are deleted.	See Table 3

The functionality differences from the OASIS MRI System to the predicate device are analyzed in the table below. Features have been added since the predicate device through the Memo to File process.

Table 3 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	• Windows 7 in Operating System is deleted from product specification. Only Windows 10 IoT is used. • CPU performance is improved from Xeon 3.5 GHz to Xeon 3.8 GHz. • Application software is changed to V7.0D. • Maximum available Presaturation pulse number is changed from eight (8) to six (6). • 2D IR, 2D TRSG and 3D TRSG sequences are deleted.			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐Technology	☐Performance
	☐Engineering	☐Materials	☐Others	☑None (See rationale statement)
HITACHI 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 same safety limits as OASIS (K192851). So safety and effectivity of the device are equivalent to the OASIS (192851).			

Substantial Equivalence

A summary decision was based on analysis of results in the table below:

Table 4 Rationale Analysis: OASIS MRI 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 (K192851). So, safety and effectively of the device are same as OASIS (K192851).
Coils	Additional or modified coils did not constitute a new intended use. There are no significant changes in technological characteristics. During transmitter coil operation, RF Coils are de-resonated by same scheme as OASIS (K192851). WIT Spine Coil is a new receiver coil has the capability of sixteen (16) channels. This is an expansion of maximum number of receiver channel compared to OASIS (K192851).
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 same safety limits as OASIS (K192851). So safety and effectivity of the device are equivalent to the OASIS (192851).

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 is considered substantially equivalent to the currently marketed predicate device 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.

- NEMA MS-1-2008 (R2014), Determination of Signal-to-Noise Ratio (SNR) In Diagnostic Magnetic Resonance Imaging (All receiver coils)
- NEMA MS 3-2008 (R2014), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images (All receiver coils)
- NEMA MS 8-2016, Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
- IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012
- IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-33 Ed. 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 diagnosis
- IEC 62304 Ed.1.1:2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

The revisions to the OASIS MRI System and standards will have no effect on the standards tests, which were conducted on the OASIS MRI System (K192851) and included in the original submission.

- NEMA MS 2-2008 (R2014), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 4-2010, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
- NEMA MS 5-2018, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging

In addition, tests were conducted on the new WIT Spine Coil, which includes 16 channels.

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 each applicable new feature, which is the WIT Spine Coil, and that we judged to be sufficient to evaluate clinical usability.

Conclusions

It is the opinion of Hitachi, 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 (K192851).