February 21, 2020

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

Re: K192851
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: January 22, 2020
Received: January 24, 2020

Dear Mr. 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192851

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
Contact:	Aaron Pierce
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Date:	January 18, 2019

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 (K093044)
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 MRI system w/V6.0F is equivalent to the OASIS MRI (K093044) with the following exceptions, which were added to the product specification:

- Micro coil (S) and Foot/Ankle coils
- Windows 7 and 10 IoT in Operating System
- Xeon 3.5GHz in CPU platform
- V6.0F Application software

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 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 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 in Table 2.

Table 2 Comparison: Hardware

ITEM		PREDICATE DEVICE OASIS (K093044)	SUBJECT DEVICE OASIS V6.0F	DIFFERENCE
System	Standards Met	NEMA: MS 1, MS 2, MS 3, MS 4, MS 5, MS7, MS 8, IEC: 60601-1, 60601-1-1, 60601-1-2, 60601-1-4, 60601-2-33	NEMA: MS 1, MS 2, MS 3, MS 4, MS 5, MS 8, IEC: 60601-1, 60601-1-2, 60601-2-33, 62304	See Table 3
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 ±100 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	108.3 dBA	126.3 dBA	See Table 3
	Leq	106.2 dB	119 dBA	See Table 3
RF System	Transmitter channels	2	2	No
	Peak Envelop Power	18 kW	18 kW	No
	Duty Cycle	60% (Gating max), 10% at full power	60% (Gating max), 10% at full power	No
	RF receiver channel	8	8	No

The hardware differences from the OASIS MRI system w/V6.0F to the predicate device 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	There are no significant hardware changes that affect technological characteristics and safety.			
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 (K093044). So, safety and effectively of the device are same as OASIS (K093044)			

The technological characteristics in regards to coils of the OASIS MRI system w/V6.0F and the predicate are listed in Table 4.

Table 4 Comparison: RF Coils

ITEM		PREDICATE DEVICE OASIS (K093044)	SUBJECT DEVICE OASIS V6.0F	DIFFERENCE
RF Coils	Transmit Coil	T/R Body	T/R Body	No
	Receiver Coils	QD Head	N/A	See Table 5
		Rapid Head	Rapid Head	No
		Rapid Body	Rapid Body	No
		Rapid Knee	Rapid Knee	No
		Rapid C-spine	Rapid C-spine	No
		Rapid Wrist	Rapid Wrist	No
		Rapid Shoulder	Rapid Shoulder	No
		Large Joint	Large Joint	No
		N/A	Micro coil (S)	See Table 5
		N/A	Foot/Ankle coil	See Table 5

The coil differences from the OASIS MRI system w/V6.0F to the predicate device 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	Micro coil (S) and Foot/Ankle coil are added and the QD Head coil is deleted. The performance and technological characteristics of the coils are the same as OASIS (K093044).			
Significant Changes	☐ Manufacturing Process	☐ Labeling	☐Technology	☐Performance
	☐Engineering	☐Materials	☐Others	☑None (See rationale statement)
HITACHI Rationale Statement	Modified functions don't 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 (K093044).			

The technological characteristics in regards 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	Going from Windows XP to Windows 7 and 10 IoT	See Table 7
CPU Platform	Going from Dual Xeon 2.8GHz to Xeon 3.5GHz	See Table 7
Application Software	Going from V2.1B to V6.0F	See Table 7
Scan Tasks	Auto Pose is available	See Table 7
2D Processing Tasks	Image Division, R2/R2* calculation and VIVID image are available.	See Table 7
3D Processing Tasks	None	No
Analysis Tasks	Color FA, AD, RD, Computed DWI and volume flow analysis are available.	See Table 7
Maintenance Tasks	None	No
Viewport Tools	SIR Map is available	See Table 7
Film, Archive Tools	None	No
Network Tools	None	No
Protocol Enhancements	BSI, ADAGE, Multi-b measurement, k-RAPID, T2* Relax Map, RADAR (2D GE, 3D GE, 2D TOF, 3D TOF, 2D Soft GE, 2D Soft FSE, 2D Soft FIR, 2D Soft SE, and 3D Soft TOF), Enhanced PC,Soft Sound Package (2D Soft SE, 2D Soft FSE, 2D Soft FIR, 3D Soft TOF, 2D Soft GE, and 2D Soft SARGE), Advanced contrast enhanced abdominal imaging, and BeamNavi are available.	See Table 7
Pulse Sequences	3D RSSG EPI, T2 RELAXMAP, 3D isoFSE, 2D FatSepRSSG, 3D FatSepRSSG, 2D FatSepFSE, 2D opFSE, 2d opFIR, 3D opFSE, 2D PBSG, 3D PBSG, 2D Soft SE, 2D Soft FSE, 2D soft FIR, 3D Soft TOF, 2D Soft GE, and 2D Soft SARGE are available.	See Table 7

The functionality differences from the OASIS MRI System to the predicate device are analyzed in Table 7. Features have been added since the predicate device through the Memo to File process.

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	• Windows 7 and 10 IoT in Operating System are added to product specification. • Xeon 3.5GHz in CPU platform is added to product specification. • Auto Pose in the Scan Tasks is added to product specification • Image Division, R2/R2* calculation of Parameter Analysis, and VIVID image in the 2D Processing Tasks are added to product specification. • Color FA, Ad, RD, Computed DWI of DWI Analysis and volume flow of Velocity Analysis in the Analysis Tasks category are added to product specification. • SIR Map in the Viewport Tools is added to product specification. • 2D GE, 3D GE, 2D TOF, 3D TOF, 2D Soft GE, 2D Soft FSE, 2D Soft FIR, 2D Soft SE, and 3D Soft TOF of RADAR in the Protocol Enhancements category are added to product specification. • 2D Soft SE, 2D Soft FSE, 2D Soft FIR, 3D Soft TOF, 2D Soft GE, and 2D Soft SARGE of Soft Sound Package in the Protocol Enhancements category are added to product specification. • BSI, ADAGE, Multi-b measurement, k-RAPID, T2* Relax Map, Enhanced PC, Soft Sound Package, Advanced contrast enhanced abdominal imaging, and BeamNavi in the Protocol Enhancements category are added to product specification. • 3D RSSG EPI, T2 RELAXMAP, 3D isoFSE, 2D FatSepRSSG, 3D FatSepRSSG, 2D FatSepFSE, 2D opFSE, 3D opFSE, 2D PBSG, 3D PBSG, 2D Soft SE, 2D Soft FSE, 2D soft FIR, 3D Soft TOF, 2D Soft GE, and 2D Soft SARGE in pulse sequences category are added to functional specification.			
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 (K093044). So safety and effectivity of the device are equivalent to the OASIS (K093044).			

Substantial Equivalence

A summary decision was based on analysis of Table 8.

Table 8 Rationale Analysis: OASIS MRI vs. Predicate

ITEM	Overall Rationale Analysis
Hardware	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics, safety and effectiveness.
Coils	Modified functions don't constitute a new intended use. There are no significant changes in technological characteristics, safety and effectiveness.
Functionality	Enhanced features do not constitute a new intended use. There are no significant changes in technological characteristics, safety and effectiveness. The feature set of the device is generally equivalent to the Predicate.

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 (OASIS MRI System (K093044)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Summary of Non-Clinical Testing

The OASIS MRI System at the time of the original submission (K072279) was subjected to the following laboratory standards testing.

- NEMA MS 2-2008 (R2014), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 5-2010, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- NEMA MS 8-2008, Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems

Hitachi determined the revisions to the subject system have no effect on these standards tests and therefore, would not need to be repeated.

During the V4.8 release, the OASIS MRI System was subjected to the following laboratory testing:

- NEMA MS 4-2010, Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices

Hitachi determined the revisions to the subject system have no effect on this standard test and therefore, would not need to be repeated.

The predicate coils at the time of their clearance were subject to the following laboratory testing:

- NEMA MS 1-2008 (R2014), Determination of Signal-to-noise Ratio (SNR) in Diagnostic Magnetic Resonance Images (Micro coil, Foot/Ankle coil only)
- NEMA MS 3-2008 (R2014), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images (Micro coil, Foot/Ankle coil only)

Hitachi determined only the new Micro coil and Foot/Ankle coil would need to be tested.

In addition, Hitachi conducted the following standards tests on the subject system:

- AAMI / ANSI 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 60601-1-2 Edition 4.0 2014-02, medical electrical equipment - Part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - 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 diagnostic.
- IEC 62304 Ed.1.0:2006, medical device software - software life cycle processes.

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 and that we judged to be sufficient to evaluate clinical usability.

Conclusions

It is the opinion of Hitachi, the OASIS MRI system w/V6.0F is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the OASIS MRI System (K093044).