MRI Division, Beijing Wandong Medical Technology Co., Ltd.
℅ Zhou Lu
Quality Engineer
No.7 Sanjianfang Nanli, Chaoyang District
Beijing, Beijing 100024
CHINA

January 29, 2021

Re: K192650
Trade/Device Name: i_Space 1.5T Superconducting Magnetic Resonance Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: December 17, 2020
Received: December 22, 2020

Dear Zhou Lu:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192650

Device Name

i_Space 1.5T Superconducting Magnetic Resonance Imaging System

Indications for Use *(Describe)*

i_Space 1.5T Superconducting Magnetic Resonance Imaging System is an imaging device, which is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MRI System produces transverse, sagittal, coronal, and oblique images that display the internal structure of the head, body, or extremities. The images produced by the MRI 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.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K192650

1 Submitter's information

1.1 Name: MRI Division, Beijing Wandong Medical Technology Co., Ltd.

1.2 Address: NO.38, Chaoyang Road, Chaoyang District, Beijing 100024, China

1.3 Telephone number: +86 10 65794660

1.4 Fax number： +86 10 65477303

1.5 Contact person: Mr. Wang Huan

1.6 Date of prepared: 01/09/2021

2 Device's information

2.1 Classification name: Magnetic Resonance Diagnostic Device

2.2 Product code: LNH

2.3 Trade/Proprietary name: i_Space 1.5T Superconducting Magnetic Resonance Imaging System

2.4 Common Name: Superconducting Magnetic Resonance Imaging System

2.5 Regulation number: 21 CFR 892.1000

2.6 Review panel: Radiology

3 Identification of Predicate Devices

3.1 510K Number: K052172

3.2 Manufacturer: Hitachi Medical Systems America, Inc.

3.3 Trade Name: HHF1 Magnetic Resonance Imaging System

4 Indications for Use

i_Space 1.5T Superconducting Magnetic Resonance Imaging System is an imaging device, which is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MRI System produces transverse, sagittal, coronal, and oblique images that display the internal structure of the head, body, or extremities. The images produced by the MRI 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.

5 Device Description

5.1 Function

i_Space 1.5T Superconducting Magnetic Resonance Imaging System utilizes a 1.5 Tesla superconducting magnet in an open gantry design. i_Space 1.5T Superconducting Magnetic Resonance Imaging System has been designed to enhance clinical utility as compared to the HHF1 by taking advantage of the imaging properties of the 1.5T magnet.

5.2 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 s 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.

5.3 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.

6 Technological Characteristics

The technological characteristics of this device are similar to the primary predicate device. The minor differences in technological characteristics do not constitute any safety and effectiveness issue, as indicated in performance data provided. The control and image processing hardware and the base elements of the system software are identical to the predicate device.

i_Space 1.5T Superconducting Magnetic Resonance Imaging System is of comparable type and substantially equivalent to HHF1 Magnetic Resonance Imaging System (K052172) in that they are similar in technology and intended uses. Both of these systems are superconducting magnetic resonance imaging system, use gradient subsystem to provide controlled and uniform gradient magnet fields in the X, Y and Z directions, and use RF subsystem to complete the function of RF signal transmitting/receiving and processing. Image reconstruction is controlled by console that has an interactive user interface, and the system produces 2D and 3D image that can be filmed or electronically stored for future review. Both of these systems have the traditional MRI units.

The following are the safety parameter with action levels:

- Maximum Static Field
- Rated of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Levels

and performance levels:

- Specification Volume
- Signal to Noise
- Image Uniformity
- Geometric Distortion
- Slice Profile, Thickness and Gap
- High Contrast Spatial Resolution

specified by the FDA guidance document for MR Diagnostic Devices that will be

evaluated. i_Space 1.5T Superconducting Magnetic Resonance Imaging System will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the international IEC standard for safety issues with Magnetic Resonance Imaging Devices. This will assure that the performance of this device can be considered safe and effective with respect to currently available system.

7 Non-clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards.

- AAMI / ANSI ES60601-1:2005/(R)2012+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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 diagnostic
- ISO 14971 Second Edition 2007-03-01 Medical devices - Application of risk management to medical devices
- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1- 6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1 Edition 1.0 2015-02 Medical devices – Application of usability engineering to medical devices
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
- IEC 62464-1:2018 Magnetic resonance equipment for medical imaging – Part 1: Determination of essential image quality parameters
- PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology
- ISO 10993-1 Fifth Edition 2018-08 Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process
- NEMA MS 1-2008 (R2014) Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- NEMA MS 2-2008 (R2014) Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 3-2008 (R2014) 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 6-2008 (R2014) Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- NEMA MS 9-2008 (R2014) Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- NEMA MS 12-2016 Quantification and Mapping of Geometric Distortion for Special Applications
- NEMA MS 14-2019 Standard for Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems

8 Substantial Equivalence and Conclusion

Comparison of Technological Characteristics with the Predicate Device:

Comparison Item	Subject Device	Predicate Device K052172	Difference analysis
Product code	LNH	LNH	Same
Regulation No.	21 CFR 892.1000	21 CFR 892.1000	Same
Class	Ⅱ	Ⅱ	Same
Indications for use	i_Space 1.5T Superconducting Magnetic Resonance Imaging System is an imaging device, which is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation.	The HHFI MR 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.	Same

	The MRI System produces transverse, sagittal, coronal, and oblique images that display the internal structure of the head, body, or extremities.	The MR system produces transverse, coronal, sagittal, oblique, and curved crosssectional images that display the internal structure of the head, body, or extremities.	Similar, this is because transverse, sagittal, coronal, and oblique images can satisfy the i_Space 1.5T image processing function, and is substantially equivalent (SE) to the predicate device.
	The images produced by the MRI System reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance.	The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance.	Same
	The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow.	The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow.	Same
	When interpreted by a trained-physician, these images provide information that can be useful in diagnosis determination.	When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.	Same
Environment of use	Hospital	Hospital	Same
Magnet			
Type	Superconducting	Superconducting	Same
Strength	1.5 Tesla	1.5 Tesla	Same
Dimension(L× W ×H)	1596mm×2028mm×2 38 6mm	1600mm×2100mm×22 0 0mm	Similar
Dimensions of the patient-acces	600 mm	610 mm	Similar

sible bore space			
Mass	4.3ton	5150kg	Similar
Leakage flux (0.5mT)	2.5m×4.0m (Radially × Axially)	2.5m×4.0m (Radially × Axially)	Same
Gradient			
Maximum magnetic strength	33mT/m	33mT/m	Same
Maximum slew rate	128mT/m/ms	150T/m/s	Relatively small, but completely satisfied with the scanning sequence
Cooling	Water	Water	Same
RF system			
Power amplifier	20kW	Output 20kW	Same
Operator's Console			
CPU	Intel ®core dure-core	Dual core 2.13GHz	Computer performance improvement
Memory	4G	3GB	Computer performance improvement
Hard disk	500G	Storage capacity 250 GB Maximum 400,000 images	Computer performance improvement
Monitor	18'-21'TFT LCD	24 inch LCD color display	Similar
Patient Table			
Length	2600mm	2350mm	Similar
Width	730mm	700 mm (table width: 506mm)	Similar
Rang of vertical motion	Not less than 350mm	495mm-852mm	It can satisfy the clinical use demand.
Horizontal stroke	Not less than 2000mm	2800mm	It can satisfy the clinical use demand.
Imaging functions			
Method	2D Fourier transform 3D Fourier transform	2D Fourier transform 3D Fourier transform	Same
Imaging coverage	Whole body	Whole body	Same

Imaging methods	Spin Echo (SE) Fast Spin Echo Inversion Recovery Pulse Sequence Gradient Echo Pulse EPI	Spin echo Fast spin echo Inversion recovery image Gradient echo image EPI image Fast inversion recovery image MR Angiography image	Similar, but different statements.
Scan matrix	64×64 128×128 256×256 512×512 1024×1024	(64-1024)×(64-1024) Increment by 4	Same
Slice thickness	a) Typical slice thickness is 5mm, the deviation is not more than +1mm; b) Minimum slice thickness: 1mm (2D); 0.05mm(3D)	0.5-100mm (2D)0.05-10.0mm (3D)	Similar
Slice plane	Transverse plane Sagittal plane Coronal plane Oblique plane	Axial plane (Axial) Sagittal plane (Sagittal) Coronal plane (Coronal) Arbitrary oblique plane (Single/Double oblique) Arbitrary interval multi- slice Arbitrary plane multi-slice	Similar, but different statements.
FOV	Minimum is 5mm×5mm and maximum is 450mm×450mm.	5-500mm	Similar
File format	DICOM 3.0	DICOM 3.0	Same

	compatibility	compatibility	
Image processing	Scan System icon field Image layout Display and hiding out images Shutter Image display mode Selected images Images synchronization Adjust W/L Zooming images Moving images Magnify images Reset images Rotation images ROI statistics Measure distance and angel Measure point comment text Image filter MIP MPR Film MOVIE	Protocol/Task System tools Layout tool Universal tools Overlay tools Mode selection Scroll tools WW/ WL tools Magnification/Shift tools Rotation/Reverse tools ROI tools Statistical tools Measurement tools Comment tools Filter MIP MPR Filming Cine tools	Similar, but different statements.

i_Space 1.5T Superconducting Magnetic Resonance Imaging System has the same intended use and similar technological characteristics than the predicate device system, HHF1 Magnetic Resonance Imaging System, with respect to the magnetic resonance features and functionalities. The magnet, gradient, patient table, operator's console and imaging functions have the same major technological characteristics as the predicate device, which any minor differences in physical attributes do not constitute any safety and effectiveness issue, as indicated in performance data provided.

In summary, it is the opinion of Beijing Wandong Medical Technology Co., Ltd. that i_Space 1.5T Superconducting Magnetic Resonance Imaging System does not raise new questions of safety or effectiveness and is substantially equivalent to the listed predicate device, HHF1 Magnetic Resonance Imaging System (K052172).

9 Conclusions

Based on the comparison and analysis above, the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device.