August 17, 2026

Xingaoyi Medical Equipment Co.,Ltd
Zhengying ZUO
Regulatory Affair Manager
#555 Yeshan Rd.
Yuyao, Zhejiang
China

Re: K254250
Trade/Device Name: MagicScan-1.5, GreenMR Serenity 1.5T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: July 24, 2026
Received: July 24, 2026

Dear Zhengying ZUO:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254250

Please provide the device trade name(s).

MagicScan-1.5, GreenMR Serenity 1.5T

Please provide your Indications for Use below.

The MagicScan-1.5, GreenMR Serenity 1.5T system is indicated for use as a Magnetic Resonance Imaging System that produces sagittal, transverse, coronal, and oblique cross sectional images, and that display internal anatomical structure and/or function of the head, body and extremities.
These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnostic. Contrast agents may be used depending on the region of interest of the scan.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

MagicScan-1.5, GreenMR Serenity 1.5T
Magnetic Resonance Imaging System

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date Prepared: Jul 21, 2026

Manufacturer: Xingaoyi Medical Equipment Co.,Ltd
No.555 Yeshan Road,Yuyao,Zhejiang,P.R.China

Contact person: ZhengYing ZUO
Regulatory Affair Manager
Xingaoyi Medical Equipment Co.,Ltd
Tel: +86 15867341527
email: 289892155@qq.com

Identification of the Device:

Proprietary/Trade Name:	MagicScan-1.5, GreenMR Serenity 1.5T
Classification Name:	Nuclear Magnetic Resonance Imaging
Regulation Name:	Magnetic resonance diagnostic device
Regulation Number:	21 CFR 892.1000
Regulatory Class:	II
Product code:	LNH
Review Panel:	Radiology

Primary Predicate Device:

Proprietary/Trade Name:	United Imaging uMR 588
Classification Name:	Nuclear Magnetic Resonance Imaging
Regulation Name:	Magnetic resonance diagnostic device
Regulation Number:	21 CFR 892.1000
Regulatory Class:	II
Product code:	LNH
Review Panel:	Radiology
Submitter/510(k) Holder:	Shanghai United Imaging Healthcare Co., Ltd.
Clearance:	K183137 (cleared Jan 11, 2019)

Device Description:

The MagicScan-1.5/ GreenMR Serenity 1.5T Magnetic Resonance Imaging System is a 1.5T superconducting magnetic resonance diagnostic device with a 60cm size patient bore. It consists of components such as magnet, RF power amplifier, RF coils, gradient power amplifier, gradient coils, patient table, spectrometer, computer, equipment cabinets, power distribution system,

internal communication system, and vital signal module etc. The MagicScan-1.5 / GreenMR Serenity 1.5T Magnetic Resonance Diagnostic Device is designed to conform to NEMA and DICOM standards.

Indications for Use:
The MagicScan-1.5, GreenMR Serenity 1.5T system is indicated for use as a Magnetic Resonance Imaging System that produces sagittal, transverse, coronal, and oblique cross sectional images, and that display internal anatomical structure and/or function of the head, body and extremities.
These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnostic. Contrast agents may be used depending on the region of interest of the scan.

Comparison with Predicate Device:
The MagicScan-1.5, GreenMR Serenity 1.5T and its predicate device, the United Imaging uMR 588 (K183137), have the equivalent intended use, and similar physical characteristics.

Table 1: Comparison with Predicate Device

Item	**Subject Device** MagicScan-1.5, GreenMR Serenity 1.5T	**Predicate Device** United Imaging uMR 588 (K183137)	**Comments**
General			
Product Code	LNH	LNH	Same
Regulation No.	21 CFR 892.1000	21 CFR 892.1000	Same
Class	II	II	Same

Item	Subject Device MagicScan-1.5, GreenMR Serenity 1.5T	Predicate Device United Imaging uMR 588 (K183137)	Comments
Indications for use	The MagicScan-1.5, GreenMR Serenity 1.5T system is indicated for use as a magnetic resonance diagnostic device that produces sagittal, transverse, coronal, and oblique cross sectional images, and that display internal anatomical structure and/or function of the head, body and extremities. These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnostic. Contrast agents may be used depending on the region of interest of the scan.	The uMR 588 system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional images, spectroscopic images, and that display internal anatomical structure and/or function of the head, body and extremities. These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnostic. Contrast agents may be used depending on the region of interest of the scan.	Equivalent Indications for use is Less than predicate device. The subject device does not support spectroscopic images. Note 1.
Magnet system			
Type of Magnet	Superconducting	Superconducting	Same
Field Strength	1.5 Tesla	1.5 Tesla	Same
Patient-accessible bore dimensions	60cm	60 cm	Same
Type of Shielding	Actively shielded,EIS technology	Actively shielded, EIS technology	Same
Magnetic stability	<0.1ppm/h	<0.1ppm/h	Same

Item	Subject Device MagicScan-1.5, GreenMR Serenity 1.5T	Predicate Device United Imaging uMR 588 (K183137)	Comments
Magnet Homogeneity	≤ 0.450 ppm @ 40cm DSV ≤ 0.040 ppm @ 30cm DSV ≤ 0.020 ppm @ 20cm DSV ≤ 0.003 ppm @ 10cm DSV	≤ 0.450 ppm @ 40cm DSV ≤ 0.040 ppm @ 30cm DSV ≤ 0.020 ppm @ 20cm DSV ≤ 0.003 ppm @ 10cm DSV	Same
Type of coolant	MagicScan-1.5: Liquid helium in the magnet，Helium gas in the closed-loop compressor/cold head refrigeration circuit; GreenMR Serenity 1.5T: No liquid helium in the magnet, Helium gas in the closed-loop compressor/cold head refrigeration circuit.	Liquid helium in the magnet，Helium gas in the closed-loop compressor/cold head refrigeration circuit;	MagicScan-1.5: same as the predicate device；GreenMR Serenity 1.5T: different cooling mechanism from predicate. The magnet contains no liquid helium. See Note 2.
Liquid helium capacity	MagicScan-1.5: Liquid helium - 1000L in the magnet, Helium gas - in the closed-loop compressor/cold head refrigeration circuit.(one compressor and one cold head)； GreenMR Serenity 1.5T: liquid helium - 0L in the magnet, Helium gas - in the closed-loop compressor/cold head refrigeration circuit.（two compressors and two cold heads).	Liquid helium - 1000L in the magnet； Helium gas - in the closed-loop compressor/cold head refrigeration circuit.(one compressor and one cold head).	MagicScan-1.5: same as the predicate device；GreenMR Serenity 1.5T: different cooling mechanism from predicate，the magnet contains no liquid helium. See Note 2.

Item	Subject Device MagicScan-1.5, GreenMR Serenity 1.5T	Predicate Device United Imaging uMR 588 (K183137)	Comments
Liquid helium consumption (normal usage state)	0 (Adopting 4K cooling head)	0 (Adopting 4K cooling head)	Same
Gradient system			
Max gradient amplitude	38 mT/m	33 mT/m	The higher gradient amplitude enables the system to achieve thinner slice thickness , smaller fields of view,and higher b-values in diffusion-weighted imaging. See Note 3.
Max slew rate	169 T/m/s	125 T/m/s	The higher slew rate enables the system to achieve thinner slice thickness , smaller fields of view,and higher b-values in diffusion-weighted imaging. See Note 4
Shielding	Active	Active	Same
Cooling	Water	water	Same
RF system			
Transmission frequency	63.87MHz	63.87 MHz	Same
Transmission bandwidth	600KHz	600KHz	Same
Maximum launch site	26uT	26uT	Same

Item	Subject Device MagicScan-1.5, GreenMR Serenity 1.5T	Predicate Device United Imaging uMR 588 (K183137)	Comments
RF power amplifier type	Water cooling	Water cooling	Same
RF power Amplifier	20kW	18KW	Better，the larger the value, the clearer the image See Note 5.
Transmission coil without tuning	Yes	Yes	Same
Number of receive channels	24	24	Same
Adjustable receiving bandwidth	yes	yes	Same
Demodulation filtering	All digital orthogonal demodulation and filtering technology	All digital orthogonal demodulation and filtering technology	Same
Dynamic range (1Hz bandwidth)	160dB	160dB	Same
Noise coefficient	<0.5dB	<0.5dB	Same
RF Coils			
Head-Neck Coil	16 channels,receive , array，volume coil	16 channels,receive，array，volume coil	Same
Body Coil	16 channels,receive, array, volume coil (It can be imaged in combination with a spinal coil)	6 channels,receive,array volume coil (It can be imaged in combination with a spinal coil)	Better,the number of channels is more, the coil better image quality and acceleration See Note 6.
Flex Coil	4 channels,receive, array surface coil	4 channels,receive, array surface coil	Same

Item	Subject Device MagicScan-1.5, GreenMR Serenity 1.5T	Predicate Device United Imaging uMR 588 (K183137)	Comments
Breast Coil	8 channels,receive,array, volume coil	10 channels, receive,array, volume coil	Channel Relatively small, but completely satisfied with the image quality See Note 7.
Spine Coil	24 channels,Receive, array, surface coil	24 channels,Receive, array, surface coil	Same
Ankle Coil	8 channels,receive, array, volume coil	4 channels,receive, array, surface coil (flex coil)	The intended use of the soft coil (Predicate device) includes the examination of the knee joint. See Note 8.
Knee Coil	8 channels,receive, array, volume coil	4 channels,receive, array, surface coil（flex coil）	The intended use of the soft coil (Predicate device) includes the examination of the knee joint See Note 8.
Shoulder coil	8 channels,receive, array, volume coil	4 channels,receive, array, surface coil (flex coil)	The intended use of the soft coil (Predicate device) includes the examination of the knee joint See Note 8
Hand Coil	8 channels,receive, array, volume coil	8 channels,receive, array, volume coil	Same
Patient table			

Item	**Subject Device** MagicScan-1.5, GreenMR Serenity 1.5T	**Predicate Device** United Imaging uMR 588 (K183137)	**Comments**
Dimensions	2500 mm (L) × 600 mm (W) × (580mm-860mm) (H)	2640 mm(L) X 880 mm(W)×(520-640) mm(H)	Similar See Note 9.
Maximum supported patient weigh	250 Kg	250 Kg	Same
Maximum speed of horizontal movement	20cm/s	20cm/s	Same
Support scanning range	150cm	150cm	Same
Accessories			
Vital Signal Gating	Support RG signal triggering the scan	Support ECG/Respiratory/Pulse signal triggering the scan	Equivalent See Note 10.

Table 2 Comparison of the Application Software Features

Item	Subject Device MagicScan-1.5, GreenMR Serenity 1.5T	Predicate Device United Imaging uMR 588 (K183137)	Comments
Standard sequences and parameters			
2D spin echo sequence			
Scan matrix	128X128	128X128	Same
TR（min）	6.8ms	6.8ms	Same
TE（min）	2.4ms	2.4ms	Same
2D fast spin echo sequence			
Scan matrix	128X128	128X128	Same
TR（min）	6.8ms	6.8ms	Same
TE（min）	2.6ms	2.6ms	Same
Slice thickness（min）	0.1mm	0.1mm	Same
Echo spacing（min）	2.4ms	2.4ms	Same

Echo train length（ETL)）	1024	1024	Same
3D gradient echo (3D GRE)			
Scan matrix	128X128	128X128	Same
TR（min）	1ms	1ms	Same
TE（min）	0.4ms	0.4ms	Same
Slice thickness（min）	0.05mm	0.05mm	Same
Plane echo			
Scan matrix	128X128	128X128	Same
TR（min）	5ms	5ms	Same
TE（min）	1ms	1ms	Same
Slice thickness（min）	0.1mm	0.1mm	Same
Echo spacing（min）	0.4ms	0.4ms	Same
TR（min）	5ms	5ms	Same
TE（min）	1ms	1ms	Same

Table 3: Comparison difference Analysis

Note 1	The indications for use of the subject device are covered by the indications for use of the predicate device. Spectroscopic images is not intended to be used with the subject device. The less indication for use of the subject device does not impact safety and effectiveness.
Note 2	The subject device of GreenMR Serenity 1.5T contains no liquid helium in the magnet. In the event of a quench, there is no cryogenic liquid boil-off or gas release into the examination room. The difference does not impact safety and effectiveness.
Note 3	The max gradient amplitude of the proposed device is larger than the predicate device. Peripheral nerve stimulation and cardiac stimulation was controlled according to IEC 60601-2-33. The difference does not impact safety and effectiveness.
Note 4	The max slew rate of the proposed device is larger than the predicate device. Peripheral nerve stimulation and cardiac stimulation was controlled according to IEC 60601-2-33. The difference does not impact safety and effectiveness.
Note 5	The power of RF power amplifier for subject device is larger her than the predicate device，the subject device with larger power is benefit for image quality. The difference does not impact safety and effectiveness.

Note 6	The number of the receiving channels of subject device is more than the predicate device,the subject device with more channels is benefit for image quality. The difference does not impact safety and effectiveness.
Note 7	The number of receiving channels is fewer than the predicate device. It is a little difference, it completely satisfied with the image quality. The effects was evaluated with clinical images. The difference does not impact safety and effectiveness.
Note 8	The intended use of predicate device includes the subject device,the number of receiving coil of subject device is more than the predicate device,the more channels is benefit for image quality. The difference does not impact safety and effectiveness.
Note 9	The dimensions of patient table of subject device are similar to the predicate device, which can satisfy clinical application. The difference does not impact safety and effectiveness.
Note 10	The RG of subject device is covered by predicate device,the RG is same as predicate device. The difference does not impact safety and effectiveness.

Technology:
The MagicScan-1.5, GreenMR Serenity 1.5T employs the same fundamental scientific technology as its predicated device.

Determination of substantial equivalence:
The Proposed MagicScan-1.5, GreenMR Serenity 1.5T are substantially equivalent to the predicate United Imaging uMR 588 (K183137) with regards to intended use, image capabilities, technological characteristics, and safety effectiveness.

Comparison Analysis
As Table 3: Comparison difference Analysis, The subjected device and the predicted device are identical in technological characteristics, including design, material, principle of operation, etc. They are similar in technical specification. The differences between the proposed device and the predicate device will not raise any new issues of safety or effectiveness. They can demonstrate substantial equivalence with predicate device.

Summary of Non-clinical test:
The MagicScan-1.5, GreenMR Serenity 1.5T were evaluated for biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to

comply with applicable medical device safety standard, The MagicScan-1.5, GreenMR Serenity 1.5T complies with voluntary standards:

1. ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
2. 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
3. IEC/TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
4. □IEC 60601-2-33 Ed. 4:2022 Medical Electrical Equipment - Part 2-33: Particular Requirements for The Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnostic
5. □IEC 60825-1: 2014, Edition 3.0, Safety of laser products - Part 1: Equipment classification and requirements.
6. ISO10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
7. ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
8. ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
9. ISO10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation
10. ISO14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
11. NEMAPS 3.1 - 3.20 2022d Digital Imaging and Communications in Medicine (DICOM) Set.
12. IEC60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
13. IEC62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices
14. IEC62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
15. ISTA 3E 2017 Similar Packaged-Products in Unitized Loads of Truckload Shipment
16. □IEC 62464-1 Edition 2.0: 2018-12, Magnetic resonance equipment for medical imaging Part 1: Determination of essential image quality

parameters.

17. NEMA MS 1-2008(R2020), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
18. NEMA MS 2-2008(R2020), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
19. NEMA MS 3-2008(R2020), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
20. NEMA MS 4-2023, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
21. NEMA MS 5-2018, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
22. NEMA MS 6-2008(R2014, R2020), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
23. NEMA MS 8-2016, Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
24. NEMA MS 9-2008(R2020), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
25. NEMA MS 10-2010, Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging.
26. NEMA MS 11-2010, Determination of Gradient-Induced Electric Fields in Diagnostic Magnetic Resonance Imaging
27. NEMA MS 12-2016 Quantification and Mapping of Geometric Distortion for Special Applications
28. IEEE Std 3333.2.1-2015 IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling
29. NEMA MS 14-2019 Standard for Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems

Summary of Clinical Tests:

The subject of this premarket submission, did not require clinical studies to support substantial equivalence.

Conclusion:

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed MagicScan-1.5, GreenMR Serenity 1.5T Magnetic Resonance Imaging System meet their intended use.

The proposed MagicScan-1.5, GreenMR Serenity 1.5T Magnetic Resonance Imaging System are similar to the predicate United Imaging uMR 588 (K183137) in terms of indications for use, design, technological characteristics, and software functions. Xingaoyi Medical Equipment Co.,Ltd considers the GreenMR Serenity 1.5T Magnetic Resonance Imaging System to be

substantially equivalent, with respect to safety and effectiveness, to the predicate device.