



Food and Drug Administration
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Jiangsu Magspin Instrument Co., Ltd.
% Mr. Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technology Service Co. Ltd.
7th Floor, Jingui Business Building, 982 Congyun Road, Baiyun District
Guangzhou, Guangdong 510420
CHINA

December 22, 2015

Re: K151074
Trade/Device Name: Magnetic Reasonance Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 20, 2015
Received: November 25, 2015

Dear Mr. Gu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a light grey shadow effect behind the text.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151074

Device Name

Magnetic Resonance Imaging System

Indications for Use (Describe)

The Magnetic Resonance Imaging System produces transversal, sagittal and coronal and oblique cross-section images of the limbs and joints. It's intended for imaging portions of the arm, including the hand, wrist, forearm, elbow, and imaging of the shoulder, and imaging portion of the leg, including the foot, ankle, calf and knee, but excluding the thigh.

Magspin's magnetic resonance imaging system is a fixed system, it produces images correspond to the spatial distribution of protons (hydrogen nuclei) that embodies magnetic resonance properties of human body and is weighted by the MR parameters such as spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and "chemical shift". When interpreted by a medical expert trained in the use of MR equipment, the images can provide diagnostically useful information.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

I. SUBMITTER

Jiangsu Magspin Instrument Co., Ltd.

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Secondary Contact Person: Leo Li

Quality Manager

Jiangsu Magspin Instrument Co., Ltd

Date Prepared: March 27, 2015

II. DEVICE

Name of Device: Magnetic Resonance Imaging System

Common/Usual Name: System, Nuclear Magnetic Resonance Imaging

Classification Names: Magnetic resonance diagnostic device (21 CFR 892.1000)

Regulation Class: II

Product Code: LNH

III. PREDICATE DEVICE

Esaote S.p. A.'s O-Scan, K092469

ADVANCED IMAGING LABORATORY, MRI SYSTEM, MODEL MAGFINDER II / AI 3200, K072850

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Magnetic Resonance Imaging System produces images of the internal structures of the patient's limbs and joints.

The MRI system consists of the following components:

- Permanent Magnetic
- Magnetic Gradient system
- Dedicated RF coils
- Spectrometer
- Radiofrequency Transmitter
- Receiver coil
- Computer equipped with imaging software
- Patient chair

V. INDICATIONS FOR USE

The Magnetic Resonance Imaging System produces transversal, sagittal and coronal and oblique cross-section images of the limbs and joints. It's intended for imaging portions of the arm, including the hand, wrist, forearm, elbow, and imaging of the shoulder, and imaging portion of the leg, including the foot, ankle, calf and knee, but excluding the thigh.

Magspin's magnetic resonance imaging system is a fixed system, it produces images correspond to the spatial distribution of protons (hydrogen nuclei) that embodies magnetic resonance properties of human body and is weighted by the MR parameters such as spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and "chemical shift". When interpreted by a medical expert trained in the use of MR equipment, the images can provide diagnostically useful information.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed Magnetic Resonance Imaging System employs the same technology as its primary predicate devices K092469 and reference device K072850.

Item	The Proposed	Primary Predicate K092469	Reference K072850
<i>Operating Modes IEC 60601-2-33 (2010-03)</i>	Normal operating mode	Normal operating mode	Normal operating mode
<i>Safety Parameter Display</i>	SAR dB/dt	SAR dB/dt	SAR dB/dt
<i>Max SAR</i>	Normal operating mode specified in IEC 60601-2-33 (2010)	Normal operating mode specified in IEC 60601-2-33 (2010)	Normal operating mode specified in IEC 60601-2-33 (2010)
<i>Max dB/dt</i>	<Normal operating mode specified in IEC 60601-2-33 (2010)	<Normal operating mode specified in IEC 60601-2-33 (2010)	<Normal operating mode specified in IEC 60601-2-33 (2010)
<i>Potential emergency condition and means provided for shutdown</i>	Shut down by Emergency Ramp Down Unit to prevent abnormal movement of patient chair	Shut down by Emergency Ramp Down Unit to prevent abnormal movement of patient chair	Shut down by Emergency Ramp Down Unit to prevent abnormal movement of patient chair

VII. NON CLINICAL TESTING PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Bench testing:

Bench testing was conducted to demonstrate the Magnetic Resonance Imaging System meets all performance standards as follows:

- IEC 60601-2-33 Edition 3.0 2010-03 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic
- NEMA MS-1-2008 Determination of Signal-to-Noise Ratio (SNR) in Diagnostic

Magnetic Resonance Imaging

- NEMA MS 5-2010 Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- NEMA MS 4-2010 Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
- NEMA MS 12-2010 Quantification and Mapping of Geometric Distortion for Special Applications
- NEMA MS 3-2008 Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- NEMA MS 8-2008 Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems
- NEMA MS 2-2008 Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Magnetic Resonance Imaging System. The device complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Animal and clinical study

The subject of this premarket submission, Magnetic Resonance Imaging System, does not require animal or clinical studies to support substantial equivalence.

VIII. CONCLUSIONS

The non-clinical data support the safety of the device. The device should perform as intended in the specified use conditions. Jiangsu Magspin Instrument Co., Ltd. considers the Magnetic Resonance Imaging System substantially equivalent to the predicate device and does not raise any new issues of safety or effectiveness.