NOV 10 2009

Appendix S1-2 Revised 510(k) Summary

1. 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 ad 21CFR 807.92.

2. General Information

Establishment:	Address:	Ningbo Xingaoyi Magnetism Co., Ltd. East Tanjialing Road, South Area of Economic Development Zone, Yuyao,Zhejiang, China, 315400
	Phone:	+86 574-62730899 - 8011
	Fax:	+86 574-62730908
Registration Number:	Xingaoyi will perform establishment registration and device listing before marking the device	
Contact Person:	Jiang, Mowen Technology Department Manager, Quality Representative Phone:+86 574-62730899 -8011 E_Mail: Jiangmowen@163.com or Jiangmowen@gmail.com	
Date of Summary Preparation:	August 31, 2009	
Device Name:	**Trade Name:**	OPER Series Open Type Permanent-Magnet MRI System, Model: OPER-0.3, OPER-0.35, and OPER-0.4
	Classification Number:	CFR 892.1000 90-LNH
	Classification:	Class II

Applicable Standards: IEC60601-1: Medical electrical equipment-Part 1 General Requirement for safety
IEC60601-2-33: Medical electrical equipment-Part 2-33 Particular requirement for the safety of magnetic resonance equipment for medical diagnosis.
21CFR subchapter J, Radiological Health
IEC60825-1 Safety of laser products-Part 1: Equipment classification, requirement and user's guide.
DICOM 3.0 PS 3.2
NEMA MS Series (MS1-MS6,MS8)

3. Safety and Effectiveness Information.

3.1 Device Description

The ***OPER Series Open Type Permanent-Magnet MRI System*** (OPER MRI) is a series of open permanent magnet MRI system, with magnetic field strength of 0.3T, 0.35T, and 0.4T, respectively. The model number for each of the corresponding system is OPER-0.3, OPER-0.35, and OPER-0.4, respectively. The OPER MRI system utilizes a permanent magnet to acquire 2D single-slice and multi-slice and 3D volume images. A wide range of pulse sequences are provided to the operator, including spin echo, fast spin echo, 2D and 3D gradient echo acquisitions. Imaging options such as inversion recovery and flow compensation are provided to suppress artifacts due to physiological motion and improve image quality.

3.2 Scientific Concepts

Magnetic Resonance (MR) is based on the fact that certain atomic nuclei have electromagnetic properties which cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nucleus used in current imaging experiments in MR. When placed in a magnetic field, there is a slight net orientation or alignment of these atomic nuclei with the magnetic field. The introduction of a short burst of radio frequency (RF) excitation of wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a reorientation of the proton's magnetization vector. When the RF excitation is removed, the proton relaxes and returns to its original orientation. The rate of relaxation is exponential, and varies with the character of the proton and its adjacent molecular environment. This reorientation process is characterized by exponential relaxation times called T1 and T2 which can be measured.

These relaxation events are accompanied by an RF emission or echo which can be measured and used to develop a representation of these emission on a three dimensional matrix. Spatial localization is encoded into the echo by varying the RF excitation and by appropriately applying magnetic field gradients in x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of NMR characteristics of the nuclei under consideration can be constructed by using image processing techniques similar to those used in CT.

3.3 Physical and Performance Characteristics

MR is capable of producing high quality anatomical images without the associated risks of ionizing radiation. In addition, the biological properties that contribute to MR image contrast are different from those responsible for x-ray image contrast. In x-ray imaging, differences in x-ray attenuation, largely based on differences in electro density are responsible for the contrast observed in x-ray images. In MR imaging, differences in proton density, blood flow, and relaxation time T1 and T2 all may contribute to image contrast. In addition, by varying the pulse sequence characteristics, images may be produced in which the contrast is primarily dependent on T1 relaxation, T2 relaxation, proton density, or the molecular diffusion of water or other proton containing molecules.

3.4 Intended Use

The *OPER Series Open Type Permanent-Magnet MRI System* is an open, whole body scanner. It is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the head, body, or extremities. The images produced by the *OPER Series Open Type Permanent-Magnet 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 determining a diagnosis.

3.5 Predicated Devices

K974212: Hitachi AIRIS II, manufactured by Hitachi Medical Systems America, Inc.

K001334: AIRIS II Version 4.1 Software, manufactured by Hitachi Medical Systems America, Inc.

K030918: Superopen 0.35T, Model NSM-P035 MRI System, manufactured by Neusoft Digital Medical Systems Co., Ltd.

3.6 Statement of Substantial Equivalence

The OPER Series Open Type Permanent-Magnet MRI System (OPER MRI) is of comparable type and substantially equivalent to Hitachi AIRIS II (K974212) and AIRIS II version 4.1 Software (K001334), and Neusoft NSM-P035 MRI System (K030918) in that they are similar in technology and intended uses. All three of these systems are open-permanent-magnet MRI Imaging System, use Gradient Subsystem to provide controlled and uniform gradient magnetic 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. All three of these systems have the traditional MRI units.

3.7 General Safety and Effectiveness Concerns

Operation of the OPER Series Open Type Permanent-Magnet MRI System (OPER MRI) is substantially equivalent to the commercially available Hitachi AIRIS II and Neusoft NSM-P35. The following are the safety parameter with action levels:

- Maximum Static Field
- Rate of Change of Magnetic Field(dB/dt)
- RF Power Deposition(SAR)
- 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 were evaluated.

Summary of Results:
The OPER Series Open Type Permanent-Magnet MRI System was evaluated to the appropriate NEMA performance standards as well as the IEC 60601-1 international medical equipment safety standards and the IEC 60601-2-33 Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. The OPER Series Open Type Permanent-Magnet MRI System is substantially equivalent to its Predicate Devices in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ningbo Xingaoyi Magnetism Co., Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

NOV 1 0 2009

Re: K092899
Trade/Device Name: OPER Series Open Type Permanent-Magnet MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: October 21, 2009
Received: October 22, 2009

Dear Mr. Job:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K092899

Appendix S1-1 Revised Indications for Use Statement

Indications For Use

510(k) Number (if known):

Device Name: OPER Series Open Type Permanent-Magnet MRI System

Indications for Use:

The OPER Series Open Type Permanent-Magnet MRI System is an open, whole body scanner. It is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the head, body, or extremities. The images produced by the OPER Series Open Type Permanent-Magnet 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 determining a diagnosis.

CAUTION: Federal (US) law restricts the use of this device to licensed professionals.

Prescription Use X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092899