

510(k) Summary

APR 10 2009

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

I. General Information

Establishment:

Name: Beijing Wandong Medical Equipment Co., Ltd.
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Beijing, CHINA, 100024
Phone: +86 10 84575844
Fax: +86 10 84575842

Registration Number: 3004859018

Contact Person: Mr. Wang Weimin
Manager,
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Date of Summary Preparation: Dec 17, 2008

Type of submission: traditional

Device Name:

- **Trade Name:** i_Open 0.5T
- **Classification Number:**
Magnetic Resonance Diagnostic Device, CFR 892.1000 90-LNH
- **Classification:** Class II
- **Performance Standards:**
None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Information.

- **Device Description:**

See Part C <Device Description> document.

- **Intended Use:**

The *i_Open* 0.5T 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 *i_Open* 0.5T system reflect the special 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.

- **Anatomical Region:** Head, Body, Spine, Extremities

- **Nucleus excited:** Proton

- **Diagnostic uses:**

T1,T2 weighted
Proton density weighted
MIP-MRA
Water suppress imaging
fat suppress imaging
MRCP

- **Imaging capabilities:**

2D Spin Echo (SE)
2D,3D Fast Spin Echo(FSE)
2D Short Tau Inversion Recovery (STIR)
2D Fluid Attenuated Inversion Recovery (FLAIR)
2D,3D Rewinded Gradient Echo (2D, 3D Rewinded-GRE)
2D, 3D Spoiled Gradient Echo (2D,3D Spoiled-GRE)
2D,3D Time of Flight Angiography (TOF)

- **Technological Characteristics (comparison with predicate device):**

The *i_Open* 0.5T is a 0.5 Tesla permanent MRI system. The magnet is mainly made of Nd-B-Fe material. The system software based on Windows®XP is an interactive program integrated with scanning control, image reconstruction, reviewing, post-processing, DICOM printing.

- **Predicated Device:**

K974212: Hitachi AIRIS II

K001334: AIRIS II Version 4.1 Software

● **Statement of Substantial Equivalence:**

The *i_Open* 0.5T is of comparable type and substantially equivalent to Hitachi AIRIS II (K974212) and AIRIS II version 4.1 Software (K001334) in that they are similar in technology and intended uses. Both of these systems are open-permanent-magnet MRI 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.

● **General Safety and Effectiveness Concerns:**

Operation of the *i_Open* 0.5T is substantially equivalent to the commercially available AIRIS II. The following are the safety parameter with action levels:

- Maximum Static Field
- Rate 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. The *i_Open* 0.5T 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.



APR 10 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Beijing Wandong Medical Equipment Co., Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K090873

Trade/Device Name: *i*_Open 0.5 T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 30, 2009
Received: March 31, 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.

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.

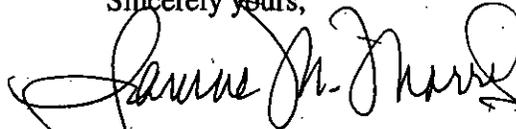
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

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

Indications for Use

510(k) Number (if known): K090873

Device Name: i_Open 0.5T

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Prescription Use

Yes

(Part 21 CFR 801

Subpart D)

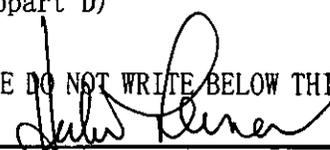
AND/OR

Over-The-Counter Use _____

(21 CFR 801 Subpart

C)

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(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K090873