K090133
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MAR 2 5 2009

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.

I. General Information

Establishment:

Name:	Beijing Wandong Medical Equipment Co., Ltd.
Address:	No.7, SanJianFang NanLi, ChaoYang District, Beijing, CHINA, 100024
Phone:	+86 10 84575844
Fax:	+86 10 84575842

Registration Number: 3004859018

Contact Person: Mr. Wang Weimin
Manager,
Phone: +86 10 84575844
Fax: +86 10 84575842
E_Mail: wmw@263.net.cn

Date of Summary Preparation: Dec 17, 2008

Type of submission: traditional

Device Name:

- **Trade Name:** *i*_Open 0.4T
- **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 0.4T 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 0.4T 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 0.4T is a 0.4 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 0.4T 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 0.4T 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 0.4T 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2009

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: K090433
Trade/Device Name: *i*_Open 0.4 T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 11, 2009
Received: March 12, 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 such 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; 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the 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" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/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): K090433

Device Name: *i*_Open 0.4T

Indications for Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090433