K091669

JUN 18 2009

新奥博为
XinAo MDT

Exhibit #3 510(k) Summary

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

Date of Submission:	April 13, 2009
Sponsor:	XinAoMDT Technology Co., Ltd. No. 2, Huaxiang Road, Econ. & Tech. Development Zone, Langfang, Hebei, 065001, China Contact Person: Ms. Guo Jinhong T: +86 0316 2596056 F: +86 0316 2596089
Correspondent:	Ms. Diana Hong / Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd Suite 8D, No. 19, Lane 999, Zhongshan No.2 Road(S) Shanghai, 200030, China
Proposed Device	Open Magnetic Resonance Imaging System, MPF3000-III
Common Name:	System, Nuclear Magnetic Resonance Imaging
Classification:	Class II, LNH, 892.1000
Predicate Device:	mStar MPF4500 (K073457)
Intended Use:	Open Magnetic Resonance Imaging System, MPF3000-III is an imaging device, and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal and oblique images that display the internal structure of the head, body or extremities. The images produced by the MR 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 (E) and flow.
Device Description:	Open Magnetic Resonance Imaging System, MPF3000-III is a 0.3T permanent magnet MRI system. It is composed of Magnet, Magnet Enclosure, Patient Table, Gradient Coil, RF Transmission Coil, RF Receiver Coil, Client PC, and Imaging Cabinet. The system software, PROSPECT, based on Windows XP® Professional is aninteractive program with user friendly interface.
Testing Conclusion:	Performance testing was conducted to validate and verify that the proposed device, Open Magnetic Resonance Imaging System, MPF3000-III met all design specifications and was substantially equivalent to the predicate device. The proposed device complies with the following standards: IEC 60601-1:1988+A1:1991+A2:1995 / IEC 60601-1-1:2000 / IEC 60601-1-2:2001+A1:2004 / NEM MS-1-2001 / NEMA MS 2-2003 / NEMA MS 3-2003 / NEMA MS 5-2003 / NEMA MS 6-1991
SE Conclusion:	Open Magnetic Resonance Imaging System, MPF3000-III, is claimed to be Substantially Equivalent (SE) to the predicate device, mStar MPF4500 (K073457)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2009

XioAo MDT Technology Co., Ltd.
% Mr Ned Devine
Senior Staff Engineer, Program Reviewer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062-2096

Re: K091669
Trade/Device Name: Open Magnetic Resonance Imaging System, MPF3000-III
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: June 3, 2009
Received: June 9, 2009

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of June 18, 2009.

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 (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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

新奥博为
XinAo MDT

Section II Indication for Use

510(k) Number: K091669
Device Name: Open Magnetic Resonance Imaging System, MPF3000-III

Indications for Use:

Open Magnetic Resonance Imaging System, MPF3000-III is an imaging device, and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal and oblique images that display the internal structure of the head, body or extremities. The images produced by the MR 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 (E) and flow.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091669