MAY 17 2012

Section III 510(k) Summary

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

The assigned 510(k) Number: k113281

1. Date of Submission: September 5, 2011

2. Sponsor
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3. Submission Correspondent
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4. Proposed Device Identification

   Proposed Device Name: MRI SYSTEMS
   Proposed Device Model: ASM-030PIII (OPENMARK III),
   ASM-040P (OPENMARK 4000),
   ASM-050P (OPENMARK 5000)
   Classification: II
   Product Code: LNH
   Regulation Number: 21 CFR 892.1000
   Review Panel: Radiology
   Intended Use Statement:
   MRI SYSTEMS, including ASM-030PIII (OPENMARK III), ASM-040P (OPENMARK 4000) and ASM-050P (OPENMARK 5000), are indicated for use as magnetic resonance diagnostic devices

(MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, and that display the internal structure and/or function of the head, body, or extremities. These images when interpreted by a trained physician yield information that may assist in diagnosis.

5. Predicate Device Identification

510(k) Number: K091580
Product Name: Pica Whole Body MRI System
Manufacturer: Time Medical Limited

6. Device Description

MRI SYSTEMS, including ASM-030PIII (OPENMARK III), ASM-040P (OPENMARK 4000) and ASM-050P (OPENMARK 5000), are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, and that display the internal structure and/or function of the head, body, or extremities. These images when interpreted by a trained physician yield information that may assist in diagnosis.

MRI SYSTEMS include a series of open permanent magnet MRI system with magnetic field strength of 0.3T, 0.4T and 0.5T respectively. The model number for each of the corresponding system is ASM-030PIII (OPENMARK III), ASM-040P (OPENMARK 4000) and ASM-050P (OPENMARK 5000) respectively. They are composed of Magnet, Magnet Enclosure, Patient Table, Gradient Coil, RF Transmission Coil, RF Receiver Coil, Client PC, and Imaging Cabinet. The system software, APEX, based on Windows XP® Professional is an interactive program with user friendly interface.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).
IEC 60601-2-33, Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic, 2002; Amendment 1, 2005, Amendment 2, 2007.
NEMA MS-1-2008, Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging.
NEMA MS 2-2008, Determination of Two-Dimensional Geometric Distortion in Diagnostic

Magnetic Resonance Images.
NEMA MS 3-2008, Determination of Image Uniformity in Diagnostic Magnetic Resonance Images.
NEMA MS 5-2003. Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging.

8. Substantially Equivalent Conclusion

The proposed device, MRI SYSTEMS, is determined to be Substantially Equivalent (SE) to the predicate device, Pica Whole Body MRI System (K091580), in respect 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

Shenzhen Anke High-tech Co., Ltd.
% Mr. Marc M. Mouser
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MAY 17 2012

Re: K113281
Trade/Device Name: MRI Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 26, 2012
Received: May 2, 2012

Dear Mr. Mouser:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section II Indications for Use

510(k) Number:
Device Name: MRI SYSTEMS

Indications for Use:

MRI SYSTEMS, including ASM-030PIII (OPENMARK III), ASM-040P (OPENMARK 4000) and ASM-050P (OPENMARK 5000), are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, and that display the internal structure and/or function of the head, body, or extremities. These images when interpreted by a trained physician yield information that may assist in diagnosis.

☒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 ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113281