Exhibit #3 510(k) Summary.

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

The assigned 510(k) Number: __K131896_____

1. Date of Submission: 06/10/2013

2. Sponsor Identification

Suzhou Anke Medical System Co., Ltd
Building K, 128 Xingpu Road. Suzhou Industrial Park, Jiangsu, 215126, China

Establishment Registration Number: Not yet registered

Contact Person: Weijie Xia
Position: Registration specialist
Tel: +86-10-51530223
Fax: +86-512-62956068
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3. Submission Correspondent

Ms. Diana Hong & Mr. Tarzan Wang
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Name: SuperVan 1.5T Magnetic Resonance Imaging System
Proposed Device Common Name: Magnetic Resonance Imaging System

Regulatory Information:
Classification Name: system, nuclear magnetic resonance imaging;
Classification: II;
Product Code: LNH ;
Regulation Number: 21 CFR 892.1000;
Review Panel: Radiology;

Intended Use Statement:
SuperVan 1.5T Magnetic Resonance Imaging System is a MRI system that produces transversal, sagittal and coronal and oblique cross-section images of the internal structure of the whole body. The images produced by the SuperVan 1.5T 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. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

5. Predicate Device Identification

510(k) Number: K052013
Product Name: ACHIEVA 1.5T & INTERA 1.5T family
Manufacturer: Philips Medical Systems Nederland BV

6. Device Description

The proposed device, SuperVan 1.5T, is a Magnetic Resonance Imaging System that utilizes a 1.5 Tesla superconducting magnet in an open gantry design.

It's indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transversal, sagittal and coronal and oblique cross-section images of the internal structure of the whole body. The images produced by the SuperVan 1.5T 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. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

The MRI system is composed of magnet, RF Amplifier, Gradient Amplifier, RF Coils, console, control computer, intercom system and water chiller. The system software, AnkeStation, based on Windows XP

operating system is an interactive program with user friendly interface.

7. Non-Clinical Test Conclusion

Non clinical 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 60601-1-1:2000, Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems.
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.
IEC 60601-1-2: 2007, Medical Electrical Equipment -Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility -Requirements and Tests.
IEC 62366: 2007. Medical devices - Application of usability engineering to medical devices.
ISO 10993-1: 2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
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 4-2010, Acoustic Noise Measurement Procedure for Diagnosing Magnetic.
NEMA MS 5-2010, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging.
NEMA MS 6-2008, Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging.
NEMA MS 8-2008, Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device
Product Code	LNH	Same
Regulation No.	21 CFR 892.1000	Same
Class	Class II	Same
Intended Use	SuperVan 1.5T Magnetic Resonance Imaging System is a MRI system that produces transversal, sagittal and coronal and oblique cross-section images of the internal structure of the whole body. The images produced by the SuperVan 1.5T 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. These images when interpreted by a trained physician, yield information that may assist in diagnosis.	Similar
Installation Type	Fixed	Same
Magnet Type	Super-conducting	Same
Field Strength	1.5T	Same
Coil	Head coil, neck coil, body coil, knee coil	Similar
Electrical Safety	Conforms to IEC 60601-1:1988 + A1:1991 + A2:1995, IEC 60601-2-33:2002 + A1:2005 + A2:2007	Same
EMC	Conforms to IEC 60601-1-2: 2007	Same
Patient Contact Material	Synthetic resin Acrylic acid lacquer	Similar
Biocompatibility	Conforms to the requirements of ISO 10993 series standards	Same
Label and Labeling	Conforms to FDA Regulatory Requirements	Same
Level of Concern of the Software	Moderate	Same

The proposed device and predicate devise share same classification and safety characteristics, similar intended use and technical specifications, the difference is too slight, will not affect the effectiveness and safety of proposed device.

The proposed device, SuperVan 1.5T Magnetic Resonance Imaging System, is determined to be Substantially Equivalent (SE) to the predicate device, ACHIEVA 1.5T & INTERA 1.5T family (K052013), in respect of safety and effectiveness.

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Product Name: ACHIEVA 1.5T & INTERA 1.5T family
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 28, 2014

Suzhou Anke Medical Systems Co., Ltd.
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. BOX 120-119
SHANGHAI 200120
CHINA

Re: K131896
Trade/Device Name: Supervan 1.5T Magnetic Resonance Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: January 27, 2014
Received: January 31, 2014

Dear Ms. Hong:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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. 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,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131896

Device Name
SuperVan 1.5T Magnetic Resonance Imaging System

Indications for Use *(Describe)*

SuperVan 1.5T Magnetic Resonance Imaging System is a MRI system that produces transversal, sagittal and coronal and oblique cross-section images of the internal structure of the whole body. The images produced by the SuperVan 1.5T 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. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ 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 A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

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