JUL 19 2013

Exhibit #14 510(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: ___

1. Date of Submission: August 06, 2012

2. Sponsor

   XBO Medical Systems Co., LTD
   RE Application Industrial Park, Rare Earth Hi-Tech Zone,
   Baotou, Inner Mongolia, 014030, China

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3. Submission Correspondent
   Ms. Diana Hong & Mr. Tarzan Wang
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
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   Email: info@mid-link.net

4. Proposed Device Identification

   Proposed Device Name: Magnetic Resonance Imaging System
   Proposed Device Model: Elixbo PM545

   Classification: II
   Product Code: LNH
   Regulation Number: 21 CFR 892.1000
   Review Panel: Radiology

   Intended Use Statement:

Elixbo PM545 is indicated for use as magnetic resonance diagnostic device that produces axial, sagittal, coronal and oblique cross sectional images, and that displays the anatomical and pathological information of the head, body, or extremities. When interpreted by a trained physician, these images yield information that can be useful in determining a diagnosis.

5. Predicate Device Identification

510(k) Number: K073457
Product Name: mStar MPF4500
Manufacturer: XinAo MDT Technology, Co., Ltd

6. Device Description

The proposed device, Elixbo PM545, is a Magnetic Resonance Imaging System that utilizes a 0.45 Tesla permanent magnet in an open gantry design.

It's 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.

The MRI system is composed of magnet, gradient & shimming system, RF system, spectrometer, temperature controller, patient table system, isolation transformer, respiratory gating unit, chiller and control system. The system software, Prospect, based on Windows® XP professional operating system is an interactive program with user friendly interface.

The proposed device includes twelve receiving coils which are Head Coil, Neck Coil, Knee Coil, Shoulder Coil, Wrist Coil, Breast Coil, Ankle Coil, Body Coil (14"), Body Coil (17"), Body Coil (20"), General Purpose Coil (6"), and General Purpose Coil (9").

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: 2007, Medical Electrical Equipment -Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility -Requirements and Tests.
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 5-2010, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging.

ISO 10993-5: 2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.

ISO 10993-10: 2002/Amd. 1:2006(E), Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity AMENDMENT 1.

ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

8. Substantially Equivalent Comparison and Conclusion

Table III-1 SE Comparison

ITEM	Proposed Device	Predicate Device K073457
Product Code	LNH	Same
Regulation No.	21 CFR 892.1000	Same
Class	II	Same
Intended Use	Elixbo PM545 is indicated for use as magnetic resonance diagnostic device that produces axial, sagittal, coronal and oblique cross sectional images, and that displays the anatomical and pathological information of the head, body, or extremities. When interpreted by a trained physician, these images yield information that can be useful in determining a diagnosis.	Same
Installation Type	Fixed	Same
Magnet Type	Permanent	Same
RF Amplifier Max Power	6 kW	Same
Coil	Head coil, neck coil, knee coil, body coil, wrist coil, shoulder coil, ankle coil, breast coil, general coil	Similar
Pulse Sequence	SE, GRE, FSE, FSE+FC, FSE+Sat, LSDWI, TOF2D, TOF3D, FLAIR, STIR, SPGR2D, SSFSE2D, SSFSE3D	Same
Maximum Gradient Strength	25mT/m	Same
Slew Rate	78mT/m/ms	Same
Gating/ Triggering	Respiration	Similar
Imaging Process Functions	Maximum intensity projection, image zoom & pan, pixel location & value detection, distance measurement, angle measurement, statistical analysis, filtering, image summation & subtraction and movie display	Same

Static Filed Strength	0.45T	Same
Peak and A Weighted acoustic Noise	Peak: <99dB A-weighted: 81.5dB	Same
Operation Mode	Normal	Same
Safety Parameter Display	SAR	Same
Max SAR for transmit Coil	0.0851 W/kg	Same
Max dB/dt	19.06 T/s	Similar
Potential Emergency Condition	Yes	Same
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
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	Minor Level of Concern (Image Enhance)/ Moderate Lever of Concern (Scan Control)	Same

Difference in Coil, Gating/ Triggering and Max dB/dt between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, Magnetic Resonance Imaging System Elixbo PM545, is determined to be Substantially Equivalent (SE) to the predicate devices, mStar MPF4500 (K073457), in respect of safety and effectiveness.

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

July 19, 2013

XBO Medical Systems Co., Ltd.
% Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K130658
Trade/Device Name: Magnetic Resonance Imaging System Elixbo PM545
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: May 17, 2013
Received: June 05, 2013

Dear Mr. Devine:

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,

Michael D. O'Hara for

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

Enclosure

Indications for Use

510(k) Number (if known): K130658

Device Name: Magnetic Resonance Imaging System Elixbo PM545

Indications for Use:

Elixbo PM545 is indicated for use as magnetic resonance diagnostic device that produces axial, sagittal, coronal and oblique cross sectional images, and that displays the anatomical and pathological information of the head, body, or extremities. When interpreted by a trained physician, these images yield information that can be useful in determining a diagnosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130658