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 20, 2016

Beijing East Whale Imaging Technology Co., Ltd.
% Miss Sharon Fan
Regulatory Engineer
B2-2 New City Industrial Park, No. 9 Kechuang 2nd St.,
YiZhuang, 100023 Beijing
CHINA

Re: K160984
Trade/Device Name: MultiScan G-Arm System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO, JAA
Dated: May 24, 2016
Received: May 31, 2016

Dear Miss Fan:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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

Robert Ochs, Ph.D.
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)*

K160984

Device Name
MultiScan G-Arm System

Indications for Use *(Describe)*

The B5 S is a mobile digital X-ray diagnostic system, which is intended to generate X-ray fluoroscopic image of a patient. The application includes: real-time positioning and monitoring operations in trauma surgery, orthopedics, spine surgery, and chest surgery. It is not intended to be used in interventional procedures.

The B5 S permits a qualified doctor or technologist to take a range of diagnostic exposures of spinal column, chest, abdomen, extremities, and other body parts on the patients .

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

May 17th 2016

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor: Beijing East Whale Imaging Technology Co., Ltd.

Address: B2-2 New City Industrial Park, No.9 KeChuang 2nd St., YiZhuang, 100023, Beijing, China.

Contact Name: Sharon Fan

Telephone No.: + 86 (10) 67892355- 8866

Fax No.: + 86 (10) 67082218

Email Address: fanxiaoyan@whaleimaging.com

3. Trade Name, Common Name, Classification [21 CFR807.92(a)(2)]

Trade Name: B5 S

Common Name: MultiScan G-Arm System

Classification: Image-intensified fluoroscopic X-ray system

Product code: OXO, JAA

Classification Panel: Radiology

Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

Table 1- Predicate Devices

510(k) Number	K151280
Applicant	Beijing East Whale Imaging Technology Co., Ltd.
Device Name	MultiScan G-Arm System

5. Description of the Device [21 CFR 807.92(a)(4)]

The B5 S is a mobile digital X-ray diagnostic system, which is intended to generate X-ray fluoroscopic image of a patient. The application includes: real-time positioning and monitoring operations in trauma surgery, orthopedics, spine surgery, and chest surgery. It is not intended to be used in interventional procedures.

There are two sets of X-ray tube assemblies and Image Intensifiers which are perpendicularly distributed on the G-Arm, acting as two sets of vertical X-ray source and receptor systems and providing fluoroscopy image of the patient. The two sets of X-ray tube assemblies and Image Intensifiers can operate simultaneously and separately.

The B5 S is comprised of control unit and G-Arm, the control unit and G-Arm

include below primary components.

Table 2-1 control unit Primary components list

Control Unit Major Component	Qty.
Viewing monitor	2
Exposure lamp	2
Control monitor	1
Keyboard	1
Footswitch subassembly	1
Printer(optional)	1

Table 2-2 G-Arm Primary components list

G-Arm Major Component	Qty.
Image intensifier assembly	2
X-Ray tube assembly	2
Laser light indicator(optional)	2
Steering unit (optional)	1

6. Intended Use [21 CFR 807.92(a)(5)]

The B5 S is a mobile digital X-ray diagnostic system, which is intended to generate X-ray fluoroscopic image of a patient. The application includes: real-time positioning and monitoring operations in trauma surgery, orthopedics, spine surgery, and chest surgery. It is not intended to be used in interventional procedures.

The B5 S permits a qualified doctor or technologist to take a range of diagnostic exposures of spinal column, chest, abdomen, extremities, and other body parts on the patients.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

Table 3- Major similarities and differences between subject and predicate devices

Item	Predicate Device	Subject Device (B5 S)	Remark
Applicable Standard	AAMI / ANSI ES60601-1 IEC60601-1-2 IEC60601-1-3 IEC60601-2-54	AAMI / ANSI ES60601-1 IEC60601-1-2 IEC60601-1-3 IEC60601-2-54	Same
Power apply	110/120VAC±10%，50/60Hz	110/120VAC±10%，50/60Hz	Same
Primary components	Image gantry + X-ray tube + image intensifier +view monitor + control monitor + footswitch	Image gantry + X-ray tube + image intensifier +view monitor + control monitor + footswitch	Same

Mobile or stationary	Mobile	Mobile			Same
Entrance Field Size of image intensifier	23cm(9″)	Triple-field			SE
		Normal: 23cm(9″)	Magn.1: 16cm(6″)	Magn.2: 12cm(4.5″)	
X-ray Output: Fluoroscopy	Range of X-ray tube voltage: 40—120 kV Range of X-ray tube current: 0.1—15mA	Range of x-ray tube voltage: 40—120 kV Range of x-ray tube current: 0.1-8.0ma			SE
	Manual Pulse Fluoroscopy kV: 40—120, step: 1kV mA: 0.1—15.0, step: 0.1 mA	Manual Pulse Fluoroscopy kV: 40—120, step: 1kV mA: 0.1—8.0, step: 0.1 mA			
	Automatic Pulse Fluoroscopy kV:40—120, step: 1kV mA : fixed at 8.0mA(AP&LT) or fixed at 15 mA(AP/LT)	Automatic Pulse Fluoroscopy kV: 40—120, step: 1kV mA: 8.0mA			
Type of X-ray tube	Stationary anode	Rotating anode			SE
SID	950-1250mm	890-1190mm			SE
Total equivalent filtration	7.1 mmAl(at 80kV)	7.0 mmAl(at 80kV)			SE
Over-Rotation	+/- 17 degrees	+/- 13 degrees			SE
Others	---				Same

The B5 S have the same technological characteristics as the predicate device except items in table3- Major similarities and differences between subject and predicate devices. However, the B5 S employs the same imaging concepts and fundamental scientific technology with the predicate device and has

passed all the tests in according to relevant standards. The differences will not impact the safety and effectiveness of the device.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Results of performance and compliance testing conducted on B5 S indicate conformance to all applicable standards recognized by FDA for this device.

Testing result from non-clinical demonstrates that the proposed device B5 S is as safe and effective as the predicate devices.

Non-clinical testing:

The proposed device has been tested to compliance to the following safety and performance standards:

a) AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012

Table 4-- Performed testing items of ANSI/AAMI ES60601-1

Testing items	**Result**
Power input	Pass
Humidity preconditioning treatment	Pass
Determination of applied parts and accessible parts	Pass
Legibility of markings	Pass
Durability of markings	Pass
ME equipment for connection to a power source by a plug	Pass

Internal capacitive circuits	Pass
Protective earth connection	Pass
Leakage currents	Pass
Dielectric strength	Pass
Ball pressure test	Pass
Measurement of creepage distance and air clearance	Pass
Cord anchorage	Pass
Gaps	Pass
Instability-overbalance in transport position	Pass
Instability-overbalance excluding transport position	Pass
Instability-overbalance from horizontal and vertical forces	Pass
Castors and wheels –force for propulsion	Pass
Castors and wheels –movement over a threshold	Pass
Instability from unwanted lateral movement in transport position	Pass
Instability from unwanted lateral movement excluding transport position	Pass
Audible acoustic energy	Pass
Support system	Pass
Maximum temperature during normal use	Pass
Spillage	Pass
Ingress of water or particulate matter	Pass
Cleaning	Pass
Interruption of the power supply/supply mains to ME equipment	Pass
Single fault conditions	Pass
Mechanical strength test	Pass
Transformer short circuit	Pass
Transformer overload test	Pass
ME system-leakage measurements	Pass

b) IEC 60601-1-2 Edition 3:2007-03

Table 5 – Performed testing items of IEC 60601-1-2

Testing items	**Result**
Mains terminal continuous disturbance voltage	Pass
Radiated emission	Pass
Electrostatic discharge	Pass
RF electromagnetic field immunity test	Pass
Fast transients on AC power line, signal line and interconnecting line	Pass
Injected current into AC power line, signal line and interconnecting	Pass
Surges to AC power port, signal line and interconnecting line	Pass
Variations of power frequency	Pass

c) IEC 60601-1-3 Edition 2.1 2013

Table 6--Performed testing items of IEC60601-1-3

Testing items	**Result**
Half-value layer	Pass
Focal spot to image receptor distance	Pass
Leakage radiation in the loading state	Pass
Leakage radiation when not in the loading state	Pass

d) IEC 60601-2-54 Edition 1.0 2009-06

Table 7—Performed testing items of IEC 60601-2-54

Testing items	**Result**
Test for dosimetric information	Pass
Accuracy of X-ray tube voltage	Pass

Accuracy of X-ray tube current	Pass
Determining the attenuation of residual radiation	Pass

Also the proposed device meets the provisions of Digital Imaging communications in Medicine (DICOM)

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the non-clinical result and relative information provided in this premarket notification, we concludes that B5 S is substantially equivalent to predicate devices with regard to safety and effectiveness.