DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 4, 2017

Beijing East Whale Imaging Technology Co., Ltd.
% Ms. Sharon Fan
Regulatory Affairs Manager
Unit 701, Building 1, Yongchang Industrial Park No. 3
Yongchang North Rd., BDA
Beijing, 100176
CHINA

Re: K163429
Trade/Device Name: B6
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO, JAA
Dated: November 22, 2016
Received: December 7, 2016

Dear Ms. 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)*
K163429

Device Name
B6

Indications for Use *(Describe)*
The B6 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 B6 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)

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013_510(k) Summary of Safety and Effectiveness

510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92]

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

Nov 22th, 2016

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

Name of Sponsor: Beijing East Whale Imaging Technology Co., Ltd.
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3. Trade Name, Common Name, Classification [21 CFR807.92(a)(2)]

Trade Name: B6
Common Name: MultiScan G-Arm System
Classification: Image-intensified fluoroscopic X-ray system
Product code: OXO&JAA
Regulation Number: 21 CFR 892.1650
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	K160984
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)]

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 B6 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
Control monitor	1
Keyboard	1
Footswitch (3- or 2- pedal)	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	2

The G-Arm system offers a group of motor-driven positioning features, including:

Image Intensifier Adjustment: 300 mm±10mm

G-Arm Height Adjustment: 300 mm±10mm

G-Arm Orbital Rotation: ±35°±2°

G-Arm Radial Rotation: ±45°±2°

The B6 can be operated in two different modes: Continuous fluoroscopy and Pulse fluoroscopy. Each of these two modes can be operated either manually or automatically.

So, the fluoroscopy mode can be categorized by the X-ray emitting pattern or by the control method of the imaging process, which consequently divides a fluoroscopy mode into the following four major types: Automatic Continuous Fluoroscopy, Automatic Pulse Fluoroscopy, Manual Pulse Fluoroscopy, Manual Continuous Fluoroscopy.

Besides the above four fundamental fluoroscopy modes, the G-Arm system offers two other features: ER Fluoroscopy and Half Dose Fluoroscopy (modifies only Automatic Pulse Fluoroscopy and Automatic Continuous Fluoroscopy modes)

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

The B6 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 B6 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** **B5 S**	**Subject Device** **B6**	**SE** **Remark**
K#	K160984	In process	---
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

Energy delivered	X-Ray and laser	X-Ray and laser	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
Fluoroscopy Mode	Manual Continuous Fluoroscopy Automatic Continuous Fluoroscopy Manual Pulse Fluoroscopy Automatic Pulse Fluoroscopy ER Fluoroscopy (ER) Half Dose Fluoroscopy	Manual Continuous Fluoroscopy Automatic Continuous Fluoroscopy Manual Pulse Fluoroscopy Automatic Pulse Fluoroscopy ER Fluoroscopy (ER) Half Dose Fluoroscopy	Same
Design			
Appearance design	Appearance of B5 S see the figure 1 of *"012_ Substantial Equivalence Device Comparison.pdf"*	Appearance of B6 see figure 2 of *"012_ Substantial Equivalence Device Comparison.pdf"*	Note 1
Electrical structure	The circuits regarding to Inverter, switch power supply, a part of PCB in the control unit side.	The circuits regarding to Inverter, switch power supply, a part of PCB in the G-Arm side.	Note 2
	The control panel only in the control unit side .	The control panel both in the control unit and G-Arm, but the control panel in the G-Arm side cannot control exposure.	
Constitute and structure			
Tracking wheel system	Optional	Tracking wheels is integrated in the base of G-Arm.	Note 3

Function and performance				
Ranges of loading factors	Manual Continuous Fluoroscopy kV: 40—120, step: 1kV mA: 0.1—8.0, step: 0.1 mA		Manual Continuous Fluoroscopy kV: 40—120, step: 1kV mA: 0.2— 8.0, step: 0.1 mA	Note 4
	Automatic Continuous Fluoroscopy kV: 40—120, step: 1kV mA: 7.0mA		Automatic Continuous Fluoroscopy kV: 40—120 mA: 0.2—7.0	
	Manual Pulse Fluoroscopy kV: 40—120, step: 1kV mA: 0.1—8.0, step: 0.1 mA		Manual Pulse Fluoroscopy kV: 40—120, step: 1kV mA: 0.1—15.0 (1-plane imaging)/8.0mA (2-plane imaging), step: 0.1 mA	
	Automatic Pulse Fluoroscopy kV: 40—120, step: 1kV mA: 8.0mA		Automatic Pulse Fluoroscopy kV: 40—120, step: 1kV mA: 0.1—15.0 (1-plane imaging)/8.0mA (2-plane imaging)	
	ER Fluoroscopy kV: min40, max120 mA : 8.0mA		ER Fluoroscopy kV: min40, max120 mA : 8.0mA	
	Half automatic continuous fluoroscopy: kV: 40—120, step: 1kV mA: 3.5mA		Half dose automatic continuous fluoroscopy: kV: 40—120, step: 1kV mA: 0.2-3.5mA	
	Half automatic pulse fluoroscopy: kV: 40—120, step: 1kV mA: 7.5mA		Half dose automatic pulse fluoroscopy: kV: 40—120, step: 1kV mA: 0.2—7.5mA	
movement	G-Arm Orbital rotation	±13	±35°±2°	Note 5
	G-Arm radial rotation	No G-Arm radial rotation function	±45°±2°	

	G-Arm lift distance	300 mm±10 mm	300 mm±10 mm	
	I.I. unit travel distance	300 mm±5mm	300 mm±10mm	
	Movement control	Control keys on the control panel in the control unit.	Control keys on the line control in the G-Arm.	
		The G-Arm's orbital rotation is driven by DC motor.	The G-Arm's orbital and radial rotation are driven by servo motor.	
Physical Characteristics				
SID	890-1190mm		800-1100mm	
dimension	G-Arm: 2116(min L)/ 2324(max L) x 910 (W) x1950(min H)/ 2550(max H) Control unit: 864 (L) x 1110 (W) x 1873(H)		G-Arm: 2520(min L)/ 2820(max L) x 910 (W) x 1876(min H)/ 2476(max H) Control unit: 904(L) x 1010 (W) x 1760(H)	Note 6
Weight	G-arm: ≈365 kg (with tracking wheel system) Control Unit≈ 235 kg Whole Product Gross Weight: 600 kg(with tracking wheels)		G-Arm: ≈ 520 kg Control Unit: ≈ 150 kg Whole Product Gross Weight: ≈ 670 kg	

Note1 - Appearance design

B6's appearance is more elegant and suitable for the electrical structure. This difference will not affect safety and effectiveness.

Note 2 - Electrical structure

In B6's electrical structure, only the circuit layout is changed, while the essential principle and components are the same as the predicate device. Adding additional control panel to the G-Arm base helps in better observation of the exposure conditions during surgery and more convenient adjustment of the loading factors. The image-intensifier has not been modified.

The B6 has passed all the tests in accordance to AAMI/ ANSI ES60601-1, IEC60601-1-2, IEC60601-3 and IEC60601-2-54. Therefore, this difference does not raise different questions of safety and effectiveness and that the device is as safe and effective as the predicate device.

Note 3 - Tracking wheel system

B5 S and B6 use different connection types in their tracking wheel systems. The tracking wheels of B6 are mechanically integrated with the G-Arm base, i.e., it is a part of base. The tracking wheel system of B5 S is optional. But the control principle and control process between B5 S and B6 are the same. The B6 has passed all the tests in accordance to AAMI/ ANSI ES60601-1, IEC60601-1-2, IEC60601-3 and IEC60601-2-54. Therefore, this difference does not raise different questions of safety and effectiveness and that the device is as safe and effective as the predicate device.

Note 4 - Ranges of loading factors

Loading factors of the B6 are controlled by the software, the software system has been well tested and validated. The B6 has passed all the tests in accordance to AAMI/ ANSI ES60601-1, IEC60601-1-2, IEC 60601-3 and IEC60601-2-54. Therefore, this change does not raise different questions of safety and effectiveness and that the device is as safe and effective as the predicate device.

Note 5 - Movement

Comparing with the movements of the predicate device, the B6 introduces the radial rotation of the G-Arm and the angle of the orbital rotation movement is changed from ±13° (B5 S) to ±35°±2°.

The G-Arm’s orbital and radial rotations are driven by servo motor, which meets the requirements of the associated clauses of AASI/AAMI 60601-1, making the rotation control more accurately.

The movements control keys of B5 S are incorporated into the control panel, which is located on the control unit, while the B6’s movements control keys are located on a separate movement control board (line control) on the G-Arm base. The control principle and electrical circuits between B5 S and B6 are the same. No new technology is introduced.

The B6 has passed all the tests in accordance to AAMI/ ANSI ES60601-1, IEC60601-1-2, IEC 60601-3 and IEC60601-2-54. Therefore, this change does not raise different questions of safety and effectiveness and that the device is as safe and effective as the predicate device.

Note 6 - SID & Dimension & Weight

The primary mechanical structure between predicate device and proposed device is the same. The differences with regard to the SID & Dimensions & Weight are resulted from different mechanical characteristic settings. No new technology is introduced. The B6 has passed all the tests in accordance to AAMI/ ANSI ES60601-1, IEC60601-1-2, IEC 60601-3, and IEC60601-2-54. Therefore, this difference does not raise different questions of safety and effectiveness.

The software modifications of proposed device have been verified and validated, the following table include the major changed elements.

Table 4- Major modifications of software

No.	Modified elements	section	Note
1	Separated the G-Arm's movement from Main control panel software	2.2.2&4.2.1&4.2.5&4.2.6 &4.5&5.3.1&5.5&6.5&9. 1&9.4	Better control
2	Single exposure time limit	33# of 3.2	User need
3	Use CAN bus communication	36# of 3.2&5.1&6.1&9.2.4	More stable and accurate communication
4	Increase a G-Arm control panel in the G-Arm side.	4.2.3&4.2.4&5.4&6.4&6. 5&9.5	help doctor to better see the exposure conditions and adjust the loading factors more convenience
5	Update dose report icon and BMP image save icon	4.3.1.3&4.3.1.7&9.1.2	Enhance user experience

6	kV and mA range adjust	4.4.2	Loading factors changed

The B6 have the same technological characteristics as the predicate device except items in table3-Major similarities and differences between subject and predicate devices. However, the B6 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 B6 indicate conformance to all applicable standards recognized by FDA for this device.

Testing result from non-clinical demonstrates that the proposed device B6 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 5-- Performed testing items of ANSI/AAMI ES60601-1

No.	Testing items	Result
1	Power input	Pass
2	Humidity preconditioning treatment	Pass
3	Determination of applied parts and accessible parts	Pass
4	Legibility of markings	Pass

5	Durability of markings	Pass
6	ME equipment for connection to a power source by a plug	Pass
7	Internal capacitive circuits	Pass
8	Protective earth connection	Pass
9	Leakage currents	Pass
10	Dielectric strength	Pass
11	Ball pressure test	Pass
12	Measurement of creepage distance and air clearance	Pass
13	Cord anchorage	Pass
14	Gaps	Pass
15	Instability-overbalance in transport position	Pass
16	Instability-overbalance excluding transport position	Pass
17	Instability-overbalance from horizontal and vertical forces	Pass
18	Castors and wheels –force for propulsion	Pass
19	Castors and wheels –movement over a threshold	Pass
20	Instability from unwanted lateral movement in transport position	Pass
21	Instability from unwanted lateral movement excluding transport position	Pass
22	Audible acoustic energy	Pass
23	Support system	Pass
24	Maximum temperature during normal use	Pass
25	Spillage	Pass
26	Ingress of water or particulate matter	Pass
27	Cleaning	Pass
28	Interruption of the power supply/supply mains to ME equipment	Pass
29	Single fault conditions	Pass
30	Mechanical strength test	Pass
31	Transformer short circuit	Pass

32	Transformer overload test	Pass
33	Transformer dielectric strength test	Pass
34	ME system-leakage measurements	Pass

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

Table 6 –Performed testing items of IEC 60601-1-2

No.	**Testing items**	**Result**
1	Mains terminal continuous disturbance voltage	Pass
2	Radiated emission	Pass
3	Electrostatic discharge	Pass
4	RF electromagnetic field immunity test	Pass
5	Fast transients on AC power line, signal line and interconnecting line	Pass
6	Injected current into AC power line, signal line and interconnecting line	Pass
7	Surges to AC power port, signal line and interconnecting line	Pass
8	Variations of power frequency	Pass

c) IEC 60601-1-3 Edition 2.1:2013-04

Table 7--Performed testing items of IEC60601-1-3

No.	**Testing items**	**Result**
1	Half-value layer	Pass
2	Focal spot to image receptor distance	Pass
3	Leakage radiation in the loading state	Pass
4	Leakage radiation when not in the loading state	Pass

d) IEC 60601-2-54 Edition 1.1: 2015-04

Table 8—Performed testing items of IEC 60601-2-54

No.	**Testing items**	**Result**
1	Test for dosimetric information	Pass
2	Accuracy of X-ray tube voltage	Pass
3	Accuracy of X-ray tube current	Pass
4	Determining the attenuation of residual radiation	Pass

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

The proposed device has performed the following software testing to demonstrates that the proposed device B6 is as safe and effective as the predicate devices

Table 9- software testing items

No.	Testing items	Result
1	Function of Main Control Panel Software	Pass
2	Function of main interface	Pass
3	Function of patient list	Pass
4	Function of image process	Pass
5	Function of save as	Pass
6	Function of print	Pass
7	Function of system settings	Pass
8	Function of on-line processing settings	Pass
9	Function of DICOM settings	Pass
10	Function of DICOM server	Pass
11	Others function	Pass
12	Long Time Exposure	Pass
13	High Dose Exposure	Pass
14	Pulse Exposure	Pass
15	CAN bus communication	Pass
16	Laser Aimer Control Test	Pass
17	Function of Movement control Panel Software	Pass
18	Function of G-ARM Control Panel Software	Pass

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 B6 is substantially equivalent to predicate devices with regard to safety and effectiveness.