



Food and Drug Administration
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Beijing East Whale Imaging Technology Co., Ltd.
% Miss June Li
Official Correspondent
B2-2 New City Industrial Park, No. 9 KeChuang 2nd Street
YiZhuang, Beijing, 100023
CHINA

September 30, 2015

Re: K151280
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: August 31, 2015
Received: September 2, 2015

Dear Miss Li:

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive, slightly slanted style.

Robert Ochs, Ph.D.
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)
k151280

Device Name
MultiScan G-Arm System

Indications for Use (Describe)

The DigiArc 100AU/ DigiArc 100AU+ is a mobile digital X-ray G-Arm 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 DigiArc 100AU/ DigiArc 100AU+ 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 at the age of at least eighteen.

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.

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510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92]

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

Aug 28th 2015

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: June Li

Telephone No.: + 86 (10) 67892355- 8968

Fax No.: + 86 (10) 67082218

Email Address: jqli@whaleimaging.com

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

Trade Name: DigiArc 100AU & DigiArc 100AU+

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	K131423 K141672
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 DigiArc 100AU/ DigiArc 100AU+ is a mobile digital X-ray G-Arm 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 DigiArc 100AU & DigiArc 100AU+ include below primary components.

Table 2- Primary components list

Component	Quantity
Control unit	1
Viewing monitor	2
Control monitor	1
Control panel	1
G-Arm	1
Image intensifier assembly	2
X-ray tube assembly	2
Foot switch subassembly	1
Laser aimer system(optional)	1
Tracking wheel system(optional)	1
Printer (optional)	1

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

The current modifications do not change the indications for use. As previously reported and cleared: the DigiArc 100AU/ DigiArc 100AU+ is a mobile digital X-ray G-Arm 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 DigiArc 100AU/ DigiArc

100AU+ 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 at the age of at least eighteen.

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

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

Item	Predicate device DigiArc 100AU	Predicate device DigiArc 100AU+	Proposed device DigiArc 100AU Proposed device DigiArc 100AU+	Note
Tracking wheel system and Laser aimer system	No	Yes	Optional	SE
X-ray Output: Fluoroscopy	Range of X-ray voltage: 40—110kV Range of X-ray current: 0.1—15mA	Range of X-ray voltage: 40—110kV Range of X-ray current: 0.1—15mA	Range of X-ray voltage: 40—110 kV (AU) 40—120 kV (AU+) Range of X-ray current: 0.1—15mA	SE
Total equivalent filtration	4.0 mmAl(at 80kV)	4.0 mmAl(at 80kV)	7.1 mmAl(at 80kV)	SE
Software version	1.1.0	1.3.0	DigiArc 100AU: V1.6.0.1 DigiArc 100AU+: V1.6.0.2	SE

Others	---	Same
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The design modifications do not alter the device’ s fundamental scientific technology, and the updated device has passed all the tests in according to relevant standards. The DigiArc 100AU & DigiArc 100AU+ employs the same technological characteristics as the predicate devices.

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

Results of performance and compliance testing conducted on DigiArc 100AU & DigiArc 100AU+ indicate conformance to all applicable standards recognized by FDA for this device.

Testing result from non-clinical demonstrates that the proposed device DigiArc 100AU & DigiArc 100AU+ are 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- Major testing items of AAMI/ANSI ES 60601-1

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
Audible acoustic energy	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 60601-1-3 Edition 2.0 2008

Table 5- Major testing items of IEC 60601-1-3

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

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

Table 6- Major 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

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

Table 7- Major testing items of IEC 60601-1-2

Testing items	result
Harmonics on AC mains	Pass
Voltage fluctuations on AC mains	Pass
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 line	Pass
Surges to AC power port, signal line and interconnecting line	Pass
Voltage dips and interruptions to AC power port	Pass
Variations of power frequency	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 DigiArc 100AU & DigiArc 100AU+ are substantially equivalent to predicate devices with regard to safety and effectiveness.