510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92]

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

June 19th 2014

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: 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)]

510(k) Number	K131423
Applicant	Beijing East Whale Imaging Technology Co., Ltd.
Device Name	G-Arm MultiScan System

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

The 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+ includes below primary components.

Table 1- 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	1
Tracking wheel system	1
Printer (optional):thermal or laser printer	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+ 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+ 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)]

The design modifications do not alter the device' s fundamental scientific technology.

The DigiArc 100AU+ employs the same technological characteristics as the predicate devices except items in table 2. However, it employs the same imaging concepts and fundamental scientific technology with the predicate device and the differences do not impact the safety and effectiveness of the device.

Table 2. Major differences between proposed device and predicate device

Item	Predicate device DigiArc 100AU (K131423)	Proposed device DigiArc 100AU+	Note
Tracking wheel system	No	Yes	Note 1
Laser aimer system	No	Yes	Note 2

Note1: The tracking wheel system is fixed on the G-Arm, it helps users move the G-Arm easily, design change concerning tracking wheel system is mechanical difference. There is no new technology on the mechanical design and the updated G-arm has passed all the tests in according to AAMI / ANSI ES60601-1:2005, thus this difference will not affect safety and effectiveness.

Note 2: The laser aimer system contains two sets of laser emitter. The two sets of laser emitter are respectively fixed on enclosure of the two intensifiers, acts as a patient positioning system. The laser aimer system does not change the fundamental scientific technology and has nothing to do with the imaging process. The laser classification of the laser component is 2, and it has past all the tests in according to IEC 60950-1:2006 and IEC 60825-1:2007, besides the updated device has passed all the tests in according to AAMI / ANSI ES60601-1:2005, thus this difference will not affect safety and effectiveness.

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

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

Testing result from non-clinical demonstrates that the proposed device DigiArc 100AU+ 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:

AAMI / ANSI ES60601-1:2005

IEC 60601-1-2:2007

IEC 60601-1-3:2008

IEC 60601-2-54:2009

And 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+ is substantially equivalent to predicate devices with regard to 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 31, 2014

Beijing East Whale Imaging Technology Co., Ltd.
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RA Engineer
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Yizhuang, Beijing 100023
CHINA

Re: K141672
Trade/Device Name: DigiArc 100AU+
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic system
Regulatory Class: II
Product Code: OXO, JAA
Dated: June 30, 2014
Received: July 2, 2014

Dear Ms. 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,

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): ~~In process~~ K141672

Device Name: MultiScan G-Arm System

Indications for Use: The current modifications do not change the indications for use , as previously reported and cleared.

The 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+ 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.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices and Radiological Health (OIR)

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

510(k) K141672