K090062
Page 1 of 3

Chapter III 510(k) Summary

MAY 18 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: _____

1. Device Information

Device Common Name: Solid State X-Ray Imaging Devices
Device Trade/Proprietary Name: WV1417A Digital X-ray Direct Imaging Flat Panel Detector System

Classification Information:
(1) Classification Name: Solid State X-Ray Imaging Devices
(2) Regulation Number:892.1650
(3) Product Code: MBQ
(4) Class: II
(5) Review Panel: Radiology

2. Submitter Information

Manufacturer:
Direct Digital Imaging Technology (Beijing) Inc.
#33 Building, Yuquan Wisdom Vale,
Tsinghua Science Park, #3 Min Zhuang Road
Haidian District, Beijing 100097, CHINA

Contact Person of the Submission
Ms. Diana Hong
Mr. Tarzan Wang
Suite 8D, Zhongxin Zhongshan Mansion,
No.19, Lane 999, Zhong Shan Nan Er Road
Shanghai, China 20020
Phone: +86-21-64264467
Fax: (240) 238-7587
Email: Diana.hong@mid-link.net

3. Device Description

The WV1417A Digital X-ray Direct Imaging Flat Panel Detector System is used to directly capture and convert conventional projection X-ray images to digital images. A image preview function can be displayed on a review monitor for viewing. The diagnostic image can be transmitted through LAN for diagnostic viewing and printing. The device provides digital image capture for conventional radiographic examinations, excluding fluoroscopic, angiographic and mammographic applications. The system differs from traditional X-ray systems in that instead of exposing a film for subsequent wet chemical processing to create a hardcopy image, a device called a detector array is used to capture the image in electronic form. The digital data are then used to produce hardcopy and softcopy images.

The WV1417A Digital X-ray Direct Imaging Flat Panel Detector System (Fig.VI-1) is composed of the following:

A detector array is used to capture the diagnostic image.

An array controller is used to control detector array, harmonize the working between the array controller and high-voltage generator for exposal synchronization and image transmission.

A system controller is used to enter patient demographic information, initiate the exposure process, review captured images, and accept or reject captured images. The system controller is also used to send images to a hardcopy printer, workstation, or archive, and manage images temporarily stored in its database. Here, the system controller is the software device and which should install in the PC hardware system purchased by themselves of customer.

The system controller also can make some disposal for the original image, such as gain, offset and defective pixel correction.

By capturing, previewing, and storing and image, the system enables an operator to check the quality of an image at the time of exposure without having to develop a film.

K090062
Page 3 of 3

4. Intended Use

The WV1417A Digital X-ray Direct Imaging Flat Panel Detector System provides a digital image capture capability for conventional radiographic examinations (excluding fluoroscopic, angiographic, and mammographic applications). The device has application wherever conventional screen-film systems are currently used.

5. Substantially Equivalence Determination

The applicant devices **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant devices are determined as safe and effectiveness.

6. Test Summary

The device is electrically operated and the electrical safety and electromagnetic compatibility following IEC 60601-1 and IEC60601-1-2 were conducted.

All the information about the device performance has provided.

The Clinical Test Report has provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Direct Digital Imaging Technology (Beijing), Inc.
% Ms. Diana Hong
General Manager
Shanghi Mid-Link Business Consulting Co., Ltd.
Suite 8D, No. 19, Lane 999, Zhongshan No. 2 Road (s)
SHANGHAI 200030
CHINA

AUG 23 2013

Re: K090062
Trade/Device Name: WV1417A Digital Direct Imaging Flat Panel Detector System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 19, 2009
Received: March 23, 2009

Dear Ms. Hong:

This letter corrects our substantially equivalent letter of May 18, 2009.

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication For Use

510(k) Number (if known): Pending K090062

Device Name: WV1417A Digital Direct Imaging Flat Panel Detector System

Indications for Use:

The WV1417A Digital X-ray Direct Imaging Flat Panel Detector System provides a digital image capture capability for conventional radiographic examinations (excluding fluoroscopic, angiographic, and mammographic applications). The device has application wherever conventional screen-film systems are currently used.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090062