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

December 16, 2015

Dexcowin Co., Ltd.
% Mr. Claude Berthoin
President
Denterprise International, Inc.
110 East Granada Blvd., Suite 207
ORMOND BEACH FL 32176

Re: K143494
Trade/Device Name: ADX6000 Portable X-Ray System; iRay A6
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: September 18, 2015
Received: September 23, 2015

Dear Mr. Berthoin:

This letter corrects our substantially equivalent letter of October 05, 2015.

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,

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K143494

Device Name
ADX6000 Portable X-Ray System (secondary Trade Name is iRay A6)

Indications for Use *(Describe)*

The ADX6000 (also known as iRay A6) is a handheld and portable general purpose X-ray system. The device uses a variable tube current with voltage from 50-80 kVp and, therefore, is limited to taking diagnostic x-rays of extremities.

It is intended to be used by a qualified and trained clinician on both adult and pediatric patients. This device is not intended for mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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."

100 E. Granada Blvd. Suite 219 Ormond Beach, FL 32176 Ph: 386-672-0450 800-323-2690

510(k) Summary

Submitter

Korea HQ: Dexcowin Co., Ltd.
606, WooLim Lions Vally II 680
GaSan-Dong, GeumChun-Gu
Seoul, Korea 153-776

U.S. Office: Dexcowin Global, Inc.
155 N. Lake Ave., Suite 800
Pasadena, CA 91101

Phone: 626-993-6716
Fax: 626-993-6601
Contact: Ryu Seung-Bum
Date: October 8, 2014

Consultant

Denterprise International, Inc.
100 East Granada Blvd., Suite 219
Ormond Beach, FL 32176

Phone: 386-506-8711
eFax: 855-235-7902

Primary Contact: Joyce St. Germain, Regulatory Executive (Joyce@510kfda.com)
Secondary Contact: Claude Berthoin, President (Claude@denterpriseintl.com)

Device Classification

Trade Names: ADX6000, iRay A6
Common Name: Portable X-Ray System
Classification Name: Mobile X-Ray System
Regulation Number: 21 CFR 892.1720
Medical Specialty: Radiology

Class:	II
Product Code:	IZL
Submission Type:	510(k)
Regulatory Class:	2

Predicate Devices

The following predicates are legally marketed, post-amendment devices:

510(k) Number:	K040046
Clearance Date:	February 2, 2004
510(k) Trade Name:	MinXray HF120/60H PowerPlus
Submitters:	Mikasa X-Ray Co., Ltd. (Tokyo, Japan) MinXray, Inc. (Northbrook, Illinois, USA)
Regulation & PC:	21 CFR 892.1720; IZL

510(k) Number:	K052721
Clearance Date:	October 27, 2005
510(k) Trade Name:	MinXray HF100H+
Submitters:	Mikasa X-Ray Co., Ltd. (Tokyo, Japan) MinXray, Inc. (Northbrook, Illinois, USA)
Regulation & PC:	21 CFR 892.1720; IZL

Device Description

The ADX6000 is a portable x-ray system intended to generate and control the emission of x-ray energy for diagnostic procedures by exposing an x-ray image receptor to ionizing radiation, typically in a hospital or clinic environment.

The x-ray source, a tube by Toshiba (tube voltage 50-80kV with 0.8 mm focal spot) is located inside the handheld device. A flat panel detector (FPD), not part of the system, connects to the device via LAN port to enable image capture, manipulation, storage, and transmission through the user interface and device software/firmware.

The operator controls three key x-ray variables to obtain the best image at minimal exposure:

1. Exposure intensity (kV)
2. Exposure dosage (mA)
3. Exposure time setting (Sec)

The ADX6000 does not have a wireless feature for transmission of data.

Indications for Use / Intended Use the same

The ADX6000 is a handheld and portable general purpose X-ray system. The device uses a variable tube current with voltage from 50-80 kVp and, therefore, is limited to taking diagnostic x-rays of extremities.

It is intended to be used by a qualified and trained clinician on both adult and pediatric patients. This device is not intended for mammography.

Comparison of Technological Characteristics with Predicates

The following table compares technological and other characteristics of the subject and predicate devices.

Feature	Dexcowin ADX6000 (Subject Device)	MinXray HF120/60H (K040046)	MinXray HF100H+ (K052721)
Intended Use	The ADX6000 is a handheld and portable general purpose X-ray system. The device uses a variable tube current with voltage from 50-80 kVp and, therefore, is limited to taking diagnostic x-rays of extremities. It is intended to be used by a qualified and trained clinician on both adult and pediatric patients. This device is not intended for mammography.	Intended for use by qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.	SAME as HF 120/60H
Mechanical			
Size: Body	322×158×178 (mm)	413×224×29.2	406×222×29.2
Weight	3.6 kg (include battery)	17.5 kg	18.6 kg
User Interface	Exposure button, on/off button selections and LCD display touch panel for exposure time selections, function selections with display.	Up-Down push buttons for kVp selections and exposure time selections with LED indicators and mAs indicators	SAME as HF 120/60H
Exposure times	0.05-1.35 seconds in 0.01 increments	0.01-0.2 Sec (in 0.01 sec Steps) 0.2-0.4 Sec (in 0.02 sec Steps) 0.4-1.0 Sec (in 0.05 sec. Steps) 1.0-5.0 Sec (in 0.1 sec. Steps)	SAME as HF 120/60H
Electrical			

Power Requirement	DC18.5V	100-260V, 50-60Hz	100-140V, 50-60Hz
Tube Voltage	50 – 80 kV 10kVstep	40 - 120 kV 2kVstep	40-100Kv 2kVstep
Tube Current	1-5 mA	60/42mA(40-50kV) 50/35mA(52-60kV) 45/31.5mA(62-70kV) 38/26.6mA(72-80kV) 33/23.1mA(82-90kV) 30/21mA(92-100kV) 20/14mA(102-120kV)	30mA(40-60kV) 25mA(62-80kV) 20mA(82-100kV)
Total Filtration	2.5 mm AL	3.2 mm AL	SAME as HF 120/60H

Both the subject ADX6000 and predicate MinXray devices are intended for mobile x-ray examination of adult and pediatric populations.

The subject device is lightweight and designed for handheld use and transport in a carry case, while the predicates are heavy enough to generally require mounting and transport on a portable stand.

The subject is DC-powered by battery, while the predicates are AC-powered via wall outlet. Both the subject and predicates are operated by push buttons and/or touch screen on the device itself.

The above comparison of technological characteristics shows the ADX6000 to be smaller, lighter, and less powerful than the predicates, with lower tube voltage and current being the more obvious examples. These variations raise no new issues of safety or effectiveness.

Performance Data

The following performance data were provided in support of the substantial equivalence determination…

1. Software – ADX6000 completed software validation and was determined to be a moderate level of concern software. The risk management test was performed in accordance with ISO 14971 and met all requirements of the standard. These tests were performed by the manufacturer and all requirements were met.

2. Electrical Safety –Accredited Testing Laboratory, Onetech Corp. performed tests for 60601-1, 60601-1-3, 60601-2-7 and 60601-2-28 and met all requirements for electrical safety.

3. Electromagnetic Compatibility (EMC)—Korea Testing Laboratory performed tests for 60601-1-2, 61000-3-2 and 61000-3-3 and met all requirements for safety.

4. Bench Testing – Performance tests for radiation protection in x-ray equipment was completed by an outside laborabory, Korea Testing Laboratory, and met the test requirements. Images from the ADX6000 were evaluated for diagnostic quality by a board certified radiologist and were approved for diagnostic quality.

Risk Analysis Information

Risks associated with the handheld design include increased operator exposure due to leakage radiation and backscatter radiation. Methods to reduce exposure include proper lead lining around the x-ray source assembly, backscatter shield, measurement of a typical exposure near and around the unit, and recommended safety precautions such as wearing personnel monitoring and protective equipment.

NOTE: The use of a tripod stand is recommended if you need the device to be more stable while taking the images to prevent blurry imaging. This is an accessory to the ADX6000.

The ADX600 has a SSD (source-skin distance) cage that is attached to the device to meet the FDA standards according to the 21 CF 1020.31 requirements of not less than 30 cm. Operators are not to remove this cage to bring the device closer to the patient. Images may be taken at a distance greater than the cage to the source, but cannot be taken closer than the cage allows.

The petition was prepared in compliances with the following FDA guidance instructions and documents: "*FDA Guidance on Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use.*"

Conclusions

The comparison of intended use and technological characteristics shows the subject device to be **at least as safe and effective as** the predicates, and, furthermore, warrants a finding of **substantial equivalence** between the ADX6000 and MinXray predicates.

The non-clinical data support the safety of the device and demonstrate that ADX6000 should perform as intended in the specified use conditions.