March 23, 2018

ECOTRON Co., Ltd.
% Mr. Dave Kim
President
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K180473
Trade/Device Name: ANYVIEW DR SERIES FPD Fluoroscopic Mobile C-Arm
ANYVIEW-240DR, ANYVIEW-320DR, ANYVIEW-500DR
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA, OXO
Dated: February 15, 2018
Received: February 22, 2018

Dear Mr. Kim:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K180473

Device Name
ANYVIEW DR SERIES FPD Fluoroscopic Mobile C-Arm
ANYVIEW-240DR, ANYVIEW-320DR, ANYVIEW-500DR

Indications for Use *(Describe)*

The ANYVIEW DR SERIES (Anyviw-500DR, Anyview-320DR, Anyview-240DR) is radiation medical equipment only used by professional radiologists. This product is designed to provide fluoroscopic and spot film images of the patient during diagnostic and interventional procedures.

This system can be applied in emergency room, operation room, cast room or etc. of hospital

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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SECTION 07

510(k) SUMMARY

1. Traditional 510(k) SUMMARY

This summary of 510(k) is being submitted in accordance with requirements of SMDA 1990 and 21 CFR Part 807.92.

Date 510K summary prepared : February 15, 2018

Submitter's Name, address, telephone number, a contact person:

Submitter's Name :	ECOTRON Co, Ltd.
Submitter's Address:	Rm 504, Hanshin IT Tower II, 47, Digital-ro 9-gil, Geumcheon-gu, Seoul, Korea
Submitter's Telephone:	Tel:+82-2-2025-3760 / Fax:+82-2-2025-3764
Contact person:	Mr. Sang Bong Lee / RA Assist Mgr
Official Correspondent:	Dave Kim (davekim@mtech-inc.net)
Address:	8310 Buffalo Speedway, Houston, TX 77025
Telephone:	+713-467-2607
Fax:	+713-583-8988

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

510K Number:	
Trade/proprietary name:	ANYVIEW DR SERIES FPD Fluoroscopic Mobile C-Arm
Model Number:	ANYVIEW-240DR, ANYVIEW-320DR, ANYVIEW-500DR
Regulation Name:	Interventional Fluoroscopic Mobile X-ray System
Regulation Number:	21 CFR 892. 1650
Regulatory Class:	Class II
Product Code:	OWB, JAA, OXO

Predicate Device

Trade Name	ANYVIEW-500R Fluoroscopic Mobile X-ray System
510(k) Clearance #	K160279
Clearance date	10/14/2016
Classification Name	Image Intensified Fluoroscopic X-ray System
Classification Panel	Radiology
CFR Section	21CFR 892.1650 (Produce Code; OWB, JAA, OXO)
Device Class	Class Ⅱ

Reference Device

Trade Name	D2RS_AT Digital Dynamic Remote System
510(k) Clearance #	K150306
Clearance date	10/10/2015
Classification Name	Image Intensified Fluoroscopic X-ray System
Classification Panel	Radiology
CFR Section	21CFR 892.1650 (Produce Code; JAA)
Device Class	Class Ⅱ

2. Device Description

The ANYVIEW DR SERIES (Anyviw-500DR, Anyview-320DR, Anyview-240DR) are mobile x-ray fluoroscopic imaging systems used by radiation experts. ANYVIEW DR SERIES are a digital fluoroscopic imaging systems with Flat Panel Detector (FPD) used in diagnostic and interventional procedures. ANYVIEW DR SERIES are composed of C-arm, x-ray generating equipment (x-ray controller, high voltage generator, x-ray tube, motor-type collimator), FPD, and workstation (console computer and monitor).

ANYVIEW imaging software is a Digital Imaging System (DIS) designed for C-arm, ANYVIEW FPD Fluoroscopic Mobile X-ray System. ANYVIEW imaging software provides useful functions to manage X-ray images obtained from ANYVIEW DR SERIES FPD Fluoroscopic Mobile X-ray System.
ANYVIEW imaging software provides various image tools. One of the most noticeable features is that the C-arm images taken during an exam are stored in the database for further review. Image data is integrated with the patient information in DICOM(OPTION) compatible format which allows compatibility with existing DICOM and PACS system.

3. Indications for Use

The ANYVIEW DR SERIES (Anyviw-500DR, Anyview-320DR, Anyview-240DR) is radiation medical equipment only used by professional radiologists. This product is designed to provide fluoroscopic and spot film images of the patient during diagnostic and interventional procedures.

This system can be applied in emergency room, operation room, cast room or etc. of hospital.

4. Summary of Design Control Risk management

ANYVIEW DR SERIES FPD Fluoroscopic Mobile X-ray System has been developed to provide the mobility of X-ray users for convenient access to patients while meeting the

critical functional requirements and international safety standards. The risks and the hazardous impact of the device design were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the device design and production phase were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design and production were successfully mitigated and accepted.

5. Summary of the technological characteristics of the device compared to the predicate device:

The indications for use and technical characteristics of ANYVIEW DR SERIES FPD Fluoroscopic system described in the 510(k) summary are similar to those of the predicate device, Anyview-500R Fluoroscopic Mobile X-ray System (K160279). Other than the digital flat panel detector, the ANYVIEW DR SERIES, the subject device, uses the same hardware, and same Anyview imaging software used for the predicate device (K160279). The difference is that the subject device is equipped with VIVIX-D 1212G digital detector whereas the predicate device is using imaging intensifier for imaging acquisition.
In addition, ANYVIEW DR SERIES Fluoroscopic system offers lower power output compared to the predicate device.

6. Substantial Equivalence

ANYVIEW DR SERIES FPD Fluoroscopic Mobile C-Arm conforms to the FDA recognized standards as like the predicate device. Based on the recognized standard conformity evidences related to electro-, mechanical-, software-, clinical-, and risk management, it's the sponsor's opinion that the subject device is a safe and effective device.

Characteristics	Anyview FPD Fluoroscopic Mobile X-ray System	Anyview-500R Fluoroscopic Mobile X-ray System (K160279)	SE-#
Intended Use	The ANYVIEW DR SERIES (Anyviw-500DR, Anyview-320DR, Anyview-240DR) is radiation medical equipment only used by professional radiologists. This product is designed to provide fluoroscopic and spot film images of the patient during	Anyview-500R mobile C-arm, fluoroscopic x-ray system, is radiation medical equipment only used by professional radiologists. This product is designed to provide fluoroscopic and spot film images of the patient during diagnostic	Same

	diagnostic and interventional procedures. This system can be applied in emergency room, operation room, cast room or etc. of hospital.		and interventional procedures. This system can be applied in emergency room, operation room, cast room or etc. of hospital.	
Energy Source	220V~230V, Single 50/60 Hz		220V~230V, Single 50/60 Hz	Same
X-ray Generator Type	HFG INVERTER TYPE		HFG INVERTER TYPE	
				Similar
Output power	Anyview-240DR	2.4 kW	5kW	#1
	Anyview-320DR	3.2 kW		
	Anyview-500DR	5.0 kW		
Fluoroscopy				
-Continuous mode	0.5-10mA		0.5-10mA	Same
-Pulsed mode	0.5-20mA		0.5-20mA	Same
-Boost mode	30mA		30mA	Same
Radiography mode				
-kV range	Anyview-240DR	40-110	40-125 kV	Similar #2
	Anyview-320DR	40-110		
	Anyview-500DR	40-125		
-mA range	Anyview-240DR	16-30	20-100 mA	Similar #2
	Anyview-320DR	15-40		
	Anyview-500DR	20-100		
-mAs range	Anyview-240DR	0.8-100	0.8~200mAs	Similar #2
	Anyview-320DR	0.8-100		
	Anyview-500DR	0.8-200		
X-ray tube type	TOSHIBA XRR-2251		TOSHIBA XR-2551	
Max kV	125kV		125kV	Same
Focal spot (S/L)	0.3 / 0.6		0.3 / 0.6	Same
Target angle	10°		10°	Same
Anode heat capacity	210 kHU		210 kHU	Same
Collimator	Open/close motorized		Open/close motorized	Same

type			
Rotation	360°	360 °	Same
Detector	Flat Panel: TFT: a-Si w/ CsI: TI scintillator	Imaging Intensifier: E5830SD-P4A (TOSHIBA)	#3
Input FOV	12 x 12 in	9inch	Similar
Central resolution	3.4 lp/mm	*54/62/70 lp/cm	#4
Laser Pointer	Included	Included	
(1) Laser Class	Class II	Class II	
(2) Max Power	5mW	5mW	Same
(3) Wavelength	655nM	655nM	Same
Viewing SW	ANYVIEW imaging software	ANYVIEW imaging software (K160279)	Same
Performance Standard	21CFR 1020.30/1020.32	21CFR 1020.30/1020.32	Same
Electrical Safety	IEC 60601-1: IEC 60601-1-2 IEC 60601-1-3 IEC 60601-2-28 IEC 60601-2-43 IEC 60601-2-54	IEC 60601-1: IEC 60601-1-2 IEC 60601-1-3 IEC 60601-2-28 IEC 60601-2-43 IEC 60601-2-54	Same

Note *: Anyview-500R imaging intensifier (K160279) has different entrance field sizes; 9/6/4.5 inch. Therefore, the central resolution for each entrance field size is different; 54/62/70 lp/cm, respectively

SSXI Performance Comparison Data (#5)

	Subject Device	Predicate device (Anyview-500R)
Model Name	VIVIX-D 1212G	E5830SD-P4A (previously cleared under K160065)
Manufacturer	VIEWORKS	TOSHIBA
Size	12 x 12 in (2048x2048 pixels)	9 in (230mm min)
MTF	54 % @ 1 lp/mm	
DQE	69 % @ 1 lp/mm	65 %
Spatial resolution	3.4 lp/mm	5.2 lp/mm

SSXI Performance Comparison Data (#6)

	Subject Device	Reference Device (D2 RS_AT Digital Dynamic Remote System)

Model Name	VIVIX-D 1212G	Pixium RF 4343 (K150306)
Manufacturer	VIEWORKS	Thalaes
Size	12 x 12 in (2048x2048 pixels)	17x17 in (2874x2840 pixels)
MTF	60% @ 1 lp/mm, 28%@2lp/mm	62% @ 1 lp/mm, 25%@2 lp/mm)
DQE	69%@ 1 lp/mm, 44%@ 2lp/mm	52% @ 1 lp/mm, 42%@2 lp/mm)
Spatial resolution	3.4 lp/mm	3.4 lp/mm

7. Difference Discussion

SE-#	SE discussion
SE-#1, #2, #3,#4	#1, #2: Both the subject device and predicate device have the same generator. Therefore, the output power ranges (kV, mA, mAs) are the same for the subject and predicate device. The maximum output power for different models of the subject device can be limited by software setting. #3, #4, #5, #6 The predicate device (Anyview-500R) is equipped with Image Intensifier. Anyview-500DR, the subject device, is equipped with a FPD which converts charging level of receiving light element to AD for output on a monitor. It reduces distortions during the data conversion. The grayscale per pixel of Image Intensifier after digital data conversion is 12bit (4096 step) whereas the grayscale of FPD is 16bit (65536 step). A higher grayscale can express X-ray image better and more details. In addition, the output resolution of the subject device is 4 times higher than the predicate device; 2K x 2K and 1K x 1K, respectively. The VIVIX-D 1212G FPD for the subject device is compared to Pixium RF 4343, FPD equipped for the reference device. Each FPD for the subject device and the reference device has the same spatial resolution of 3.4 lp/mm and demonstrates equivalent bench test performance in terms of MTF and DQE.

8. Summary of the technological characteristics of the device compared to the predicate device:

The indications for use, operating principle, and technical characteristics of the subject device described in this 510k are similar to those of the predicate device. The specifications of X-ray tube, X-ray generator, and X-ray tube anode heat content (Heating Unit) of the subject device are identical to those of the predicate device.

The primary difference is that the subject device is equipped with a flat panel detector whereas the predicate device uses image intensifier.

MTF, DQE and spatial resolution for each detector type have been studied for comparison between the subject and predicate device. The bench testing demonstrated equivalent performance between the subject and predicate device.

The pixel size (2k x 2k) of the subject device is better than the active pixel (1K x 1K) of the predicate device.

These differences do not have significant effect on safety and effectiveness compared to the predicate device.

ANYVIEW imaging software of the subject device and the predicate device is identical.

9. Description of non-clinical tests.

The subject device has been tested for electrical safety and electromagnetic compatibility. The device also complies with FDA EPRC Performance Standard: 21 CFR 1020.30-32. The software validation and verification testing was also performed. The results of nonclinical testing indicate that the subject device is as safe and effective as Anyview-500R Fluoroscopic Mobile X-ray System, the predicate device.

Compliance evidences were submitted for the following standards:

- IEC60601-1:2005 + A1 (2012)
- IEC60601-1-2:2014
- IEC60601-1-3:2008
- IEC60601-2-28:2010
- IEC60601-2-43:2010
- IEC60601-2-54:2009
- NEMA PS 3.1-3.20

The subject device meets EPRC regulation requirements.

- 21CFR1020.30
- 21CFR1020.32

10. Description of clinical tests.

No clinical data is necessary to evaluate safety or effectiveness for purposes of determining substantial equivalence of the proposed modification. Bench testing was performed to assess the device safety and effectiveness.

11. Conclusion as to Substantial Equivalence

The ANYVIEW DR SERIES (Anyviw-500DR, Anyview-320DR, Anyview-240DR), the subject device are substantially equivalent to the predicate (K160279). The intended use, the design principle, and the applicable standards for the subject device are identical to those of the predicate device. Some characteristics, for example, their appearance, the user interfaces and the detector's performance are different. However, the performance test and non-clinical consideration result demonstrate that these differences do not raise any new questions of safety and effectiveness. Therefore, it is the sponsor's opinion that the subject device appears to be as safe and effective as the predicate device.