DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 14, 2016

ECOTRON Co., Ltd
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K160279
Trade/Device Name: Anyview-500R Fluoroscopic Mobile X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA, OXO
Dated: September 30, 2016
Received: October 05, 2016

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.

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

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)*
K160279

Device Name
Anyview-500R Fluoroscopic Mobile X-ray System

Indications for Use *(Describe)*

Anyview-500R fluoroscopic mobile 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 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 04

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 : September 30, 2016

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:	K160279
Trade/proprietary name:	ANYVIEW-500R Fluoroscopic Mobile X-ray System
Regulation Name:	Image-intensified Fluoroscopic X-ray System
Regulation Number:	21 CFR 892. 1650
Regulatory Class:	II
Product Code:	OWB, JAA, OXO

Predicate Device

Trade Name	KMC-950
510(k) Clearance #	K032761
Clearance date	05/14/2004
Classification Name	Image Intensified Fluoroscopic X-ray System
Classification Panel	Radiology
CFR Section	21CFR 892.1650 (Produce Code; JAA, OWB, OXO)
Device Class	Class Ⅱ

2. Device Description

This device is a mobile x-ray fluoroscopic imaging system used by radiation experts. This device is a fluoroscopic imaging system to visualize human body's anatomical structure using a principle that x-ray generates hypophonesis difference when penetrating human body depending on tissue's density and thickness. The device is composed of main body, x-ray generating equipment (x-ray controller, high voltage generator, x-ray tube, motor-type collimator), image collecting equipment (Image Intensifier, CCD Camera) and digital imaging system (cart including computer and monitor). The product's arm is mobile and rotatable in X, Y and Z axes, which facilitates use of x-ray in every direction.

ANYVIEW imaging software is a Digital Imaging System (DIS) designed for C-arm, Anyview-500R. ANYVIEW imaging software provides useful functions to manage X-ray images obtained from Anyview 500R C-arm.
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. All these features are available in a single application program, ANYVIEW.

3. Indications for Use

Anyview-500R fluoroscopic mobile 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 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-500R 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:

Anyview-500R Fluoroscopic Mobile X-ray System described in this 510(k) has the similar indications for use and technical characteristics as the predicate device, KMC-950 (K032761) manufactured by COMED Medical Systems, Inc.

6. Substantial Equivalence

Anyview-500R Fluoroscopic Mobile X-ray System 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 Anyview-500R Fluoroscopic Mobile X-ray System is a safe and effective device.

Characteristics	Anyview-500R Fluoroscopic Mobile X-ray System (K160279)	KMC-950 (K032761)	SE-#
Intended Use	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 and interventional procedures. This system can be applied in emergency room, operation room, cast room or etc. of hospital.	The KMC-950 is intended to provided fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to digital subtraction angiography, orthopedic, neurological, abdominal, vascular, cardiac, critical care and emergency room procedures. The system may be used for other RF imaging application at physician's discretion.	Similar
Energy Source	220V~230V, Single 50/60 Hz	100V-120V or 200V-230V Single 50/60 Hz	Similar

X-ray Generator Type	HFG INVERTER TYPE	High frequency Inverter type (POSKOM)	Same
Output power	5kW	12.5W	#1
Fluoroscopy			
-Continuous mode	0.5-10mA	0.5-5mA	Similar
-Pulsed mode	0.5-20mA	0.5-5mA	#2
-Boost mode	30mA	20mA	Similar
Radiography mode			
-kV range	40-125 kV	40-120kV	Similar
-mA range	20-100 mA	20-150	Similar
-mAs range	0.8~200mAs	0.4~500 mAs	#3
X-ray tube type	TOSHIBA XR-2551	Varian RAD-99	
Max kV	125kV	120kV	Similar
Focal spot (S/L)	0.3 / 0.6	0.3 / 0.6	Same
Target angle	10°	10°	Same
Anode heat capa	210 kHU	300 kHU (HU=1.4 x Joule)	Similar
Collimator type	Open/close motorized	Open/close motorized	Same
Rotation	360 °	360 °	Same
Image Intensifier	E5830SD-P4A (TOSHIBA)	E5764SD-P4A (TOSHIBA)	
Input FOV	9inch	9inch	Same
Entrance field size	9/6/4.5 in	9/6/4.5 in	Same
Central resolution	54/62/70 lp/cm	54 lp/cm	Same
Contrast	36:1	25:1	#4
CCD Camera type	CCD	CCD	Same
Resolution	1K x 1K	512 x 512	Different
Laser Pointer	Included	N/A	
(1) Laser Class	Class II	N/A	
(2) Max Power	5mW	N/A	
(3) Wavelength	655nM	N/A	

Performance Standard	21CFR 1020.30	21CFR 1020.30	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

Image intensifier Performance Comparison Data – TOSHIBA

			Predicate device (KMC-950) (K032761)			Subject device (Anyview-500R)		
Model Name			E5764SD-P4A (previously cleared under K032761)			E5830SD-P4A (previously cleared under K160065)		
Manufacturer			TOSHIBA			TOSHIBA		
Overall Length			338±5 mm			338±5 mm		
Maximum Diameter			304±2 mm			304±2 mm		
Parameters			Normal	Magn.1	Magn.2	Normal	Magn.1	Magn.2
Output image size			20.0 ± 0.5 mm			25.2 ± 0.2 mm		
Nominal entrance field size			230	160	120	230	160	125
DQE			65	-	-	65	-	-
Conversion factor(cd.m2/μGy.s-1)			28	-	-	26	-	-
Central resolution			48	56	66	52	58	68
Contrast ratio	10% area		25	-	-	30	-	-
	10mm dia.		16	-	-	19	-	-
Weight(approx.)			18 kg			20 kg		
Power supply	Input voltage		24±1 Vdc			24±1 Vdc		
	Output voltage	Anode	30	30	30	30	30	30
		G3 Electrode (kV)	3 to 4	5 to 8	9 to 12	3 to 4	5 to 8	9 to 12
		G2 Electrode (V)	400 to 800	400 to 800	500 to 1200	400 to 800	400 to 900	500 to 1200
		G1 Electrode (V)	100 to 250	100 to 250	100 to 250	150 to 300	150 to 300	100 to 250
		Photocathode (V)	0	0	0	0	0	0
Relevant standard			IEC 1262-1 to 7			IEC 1262-1 to 7		

7. Difference Discussion

SE-#	SE discussion
SE-#1, #2, #3, #4	Anyview-500R Fluoroscopic Mobile X-ray System is equipped with high resolution CCD camera in comparison with the predicate device; 1K x 1K vs 512 x 512. Anyview-500R Fluoroscopic Mobile X-ray System requires less X-ray source and therefore less capacity for the X-ray generator and tube heat storage compared to the predicate device. Such differences in performance do not raise additional risk concerns.

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

The indications for use, mechanical components, performances and safety characteristics of Anyview-500R Fluoroscopic Mobile X-ray System described in this 510(k) are similar to those of the predicate device.

The primary differences are the specifications of X-ray tube, and X-ray generator of the subject device. The performance specifications of the subject device are lower than those of the predicate device such as the X-ray generator and X-ray tube anode heat content (Heating Unit). However Anyview-500R Fluoroscopic Mobile X-ray System is equipped with high resolution CCD camera in comparison with the predicate device; 1K x 1K vs 512 x 512. Anyview-500R Fluoroscopic Mobile X-ray System requires less X-ray source and therefore less capacity for the X-ray generator and tube heat storage compared to the predicate device.

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

9. Performance Testing/Data

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence. Safety compliance checking (including EMC, and so on) was evaluated according to the IEC Standards. ECOTRON Co., Ltd certifies conformance to Voluntary Standards covering electrical and Mechanical safety. In conclusion, the identified risk of electrical hazards was mitigated and it is the sponsor's opinion that Ayview 500-R appears to be as safety and effective as the predicate device.

10. Description of non-clinical tests.

Anyview-500R Fluoroscopic Mobile X-ray System 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 Anyview-500R Fluoroscopic Mobile X-ray System is as safe and effective as the predicate device.

Compliance evidences were submitted for the following standards:

- IEC60601-1:2005 + A1 (2012)
- IEC60601-1-2:2007
- IEC60601-1-3:2008
- IEC60601-2-28:2010
- IEC60601-2-43:2010
- IEC60601-2-54:2009
- NEMA PS 3.1-3.20

11. 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.

12. Conclusion as to Substantial Equivalence

Anyview-500R Fluoroscopic Mobile X-ray System is substantially equivalent to the predicate device KMC-950 (K032761). Both devices are very similar in the intended use, the design principle, the performance and the applicable standards. Some characteristics, for example, their appearance, the user interfaces and the capacity of X-ray generator and X-ray tube are different. However, the compliance reports, performance demonstrations and description of non-clinical review result in this submission STED provide demonstration that these differences do not raise any new questions of safety and effectiveness. Therefore, it is the sponsor's opinion that Anyview-500R Fluoroscopic Mobile X-ray System appears to be as safe and effective as the predicate device.