



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

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

July 24, 2015

Re: K151038
Trade/Device Name: EPX-Series Mobile X-ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: June 19, 2015
Received: June 25, 2015

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

For

Robert Ochs, Ph.D.
Acting 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)

K151038

Device Name

Epx-series Mobile X-ray System

Indications for Use (Describe)

This product, diagnostic X-ray system, is radiation medical equipment used by a qualified / trained physician or technician on both adult and pediatric subjects for taking diagnostic X-rays.

This product is used on hand (wrist), foot (ankle), shoulder, elbow, knee, and other body parts.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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EPX Series Diagnostic X-ray System:
F1600, F2400, F2800, F3200, F4000, F5000

SECTION 07

510(k) SUMMARY



1. Traditional 510(k) SUMMARY

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

Date 510K summary prepared : April 10, 2015

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

Trade/proprietary name: EPX Series Mobile X-ray System
F1600, F2400, F2800, F3200, F4000, F5000
Regulation Name: Mobile X-ray System
Regulation Number: 21 CFR 892.1720
Regulatory Class: II
Product Code: IZL

Predicate Device
Manufacturer : JOB Corporation
Device : PORTA 100HF
510(k) Number : K122697
Decision Date : Oct. 5, 2012



EPX Series Diagnostic X-ray System:
F1600, F2400, F2800, F3200, F4000, F5000

2. Device Description

This product, portable X-ray generator, is radiation medical equipment which can only be used by professional radiologists. It controls and marks X-ray dose within the range of X-ray exposure limited by hardware. Also it uses algorithm of X-ray output for processing and control. This portable X-ray generator requires equipment for X-ray imaging in order to generate X-ray images. Small in size, this product is convenient to carry with, and suitable for being moved around. The main body can be compatibly used with a stand. And when attached to a stand, it is easy to adjust positioning for medical imaging.

3. Indications for Use

This product, diagnostic X-ray system, is radiation medical equipment used by a qualified / trained physician or technician on both adult and pediatric subjects for taking diagnostic X-rays.

This product is used on hand (wrist), foot (ankle), shoulder, elbow, knee, and other body parts.

4. Summary of Design Control Risk management

EPX mobile X-ray series have 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:

EPX mobile X-ray series escribed in this 510(k) have the similar indications for use and technical characteristics as the predicate device, PORTA 100HF (K122697) manufactured by JOB Corporation.

6. Substantial Equivalence

EPX Series 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 is confirmed that EPX Series diagnostic X-ray system is substantially equivalent to the predicate device.

Characteristics	EPX series Mobile X-ray System (F1600, F2400, F2800, F3200, F4000, F5000)						PORTA 100HF (K122697) , JOB Corporation	SE-#
Intended Use	This product, diagnostic X-ray system, is radiation medical equipment used by a qualified / trained physician or technician on both adult and pediatric subjects for taking diagnostic X-rays. This product is used on hand (wrist), foot (ankle), shoulder, elbow, knee, and other body parts.						Intended use by a qualified/technician on both adult and pediatric subjects for taking diagnostic X-rays	Similar
Energy Source	110V~120V / 220V~240V, Single 50/60 Hz						100V-120V or 200V-240V Single 50/60 Hz	Same
User Interface	Up and down Rotary switch for kV and mAs value with 7 segment LED						Up and down Rotary switch for kV and mAs value with 7 segment LED	Same
Exposure switch	Dual stage, deadman type with curled cable.						Dual stage, deadman type with curled cable.	Same
Controls	Software based						Software based	Same
Construction	Monobloc HF generator, Medical full bridge inverter system						Monobloc HF generator, Medical full bridge inverter system	Same
High Voltage Adjustment	High frequency inverter						High frequency inverter	Same
Line Voltage Adjustment	Automatic, Dynamic						Automatic, Dynamic	Same
Exposure times (sec)	F1600	F2400	F2800	F3200	F4000	F5000	0.01 – 2.50 sec, 32 steps	Similar
	0.01~2.46 sec, 20steps	0.01-4.0 sec, 25steps	0.01-3.57 sec, 25steps	0.01-3.2 sec, 25steps	0.01-4.0 sec, 25steps	0.01-5.0 sec, 25steps		
Tube Potential (kV)	F1600	F2400	F2800	F3200	F4000	F5000	40-100kV (2kV step)	Similar
	40-90kV (1kV step)	40-100kV (1kV step)	40-120kV (1kV step)	40-100kV (1kV step)	50~110kV (1kV step)	50~110kV (1kV step)		
Tube current	F1600	F2400	F2800	F3200	F4000	F5000	30mA (40-66kV) 20mA (68kV – 100kV)	#1
	12~30mA	20~40mA	14~40mA	25~60mA	20~80mA	20~100mA		



EPX Series Diagnostic X-ray System:
F1600, F2400, F2800, F3200, F4000, F5000

mAs	F1600	F2400	F2800	F3200	F4000	F5000		
	0.4~32mAs	0.4~100mAs	0.4~100mAs	0.4~100mAs	0.4~100mAs	0.4~100mAs	0.3 mAs – 50 mAs	#2
X-ray tube	F1600	F2400	F2800	F3200	F4000	F5000		
	D-125	D-125	D-125	D-205B	OX/110-15	OX/110-15	Toshiba D-124	#3
Anode heat storage	F1600	F2400	F2800	F3200	F4000	F5000		
	50K HU	50K HU	50K HU	40k HU	42k HU	42k HU	20K HU	#4
Focal Spot	F1600	F2400	F2800	F3200	F4000	F5000		
	1.2mm	1.2mm	1.2mm	2.0mm	1.8mm	1.8mm	1.2mm	#5
Total Filtration	F1600	F2400	F2800	F3200	F4000	F5000		
	3.3mm AL.Eq @75kV	3.3mm ALEq @75kV	3.3mm ALEq @75kV	3.3mm ALEq @75kV	3mm ALEq @75kV	3mm ALEq @75kV	2.5mm AL. eq. at 100kV	#6
Collimator	Complete with 30 sec. timer and cross indication line						Complete with 30 sec. timer and cross indication line	Same
Performance Standard	21CFR 1020.30						21CFR 1020.30	same
Electrical Safety	IEC 60601-1: IEC 60601-1-3 IEC 60601-2-28 IEC 60601-1-2 IEC 60601-2-54						IEC 60601-1: IEC 60601-1-3 IEC 60601-2-28 IEC 60601-1-2 IEC 60601-2-7 IEC 60601-2-54	#7
X-ray Radiography	Conventional X-ray film or digital imaging detector						Conventional X-ray film or digital imaging detector	same

7. Difference Discussion

SE-#	SE discussion
SE-#1, #2,	<p>EPX Series mobile X-ray system performs similar or better compared to the predicate device in terms of performance specifications. For EPX-F1600, the performance specification is almost identical to the predicate device. In terms of kV, tube current. EPX-F1600 provides more segmented kV step control compared to the predicate. EPX-F2400 and EPX-F2800 have similar or higher capacity than the predicate device in terms of kV and tube current setting which may require shorter patient exposure time.</p> <p>EPX-F3200, EPX-4000 and EPX-F5000 are equipped with even higher performance specifications and higher tube current control is possible. The high voltage controls X-ray penetration and thus the contrast of the image. The tube current and exposure time affect the dose and therefore the darkness of the image.</p> <p>Such differences in performance do not raise additional risk concerns.</p>
SE-#3, #4, #5	<p>F1600, F2400, and F2800 show the same effective focal spot. The effective focal spot for F3200, F4000, and F5000 is larger than the predicate device. The effective focal spot size is controlled by the size of the actual focal spot and the anode target angle. Larger effective focal spot results wider useful beam. EPX series has larger anode heat storage than the predicate device. It refers to the capacity of the thermal energy of which the X-ray tube must be able to support and dissipate during and after an exam.</p>
SE-#6	<p>The minimum filtration reduces patient radiation dose by eliminating low energy that would otherwise be absorbed by the patient's skin.</p> <p>Positive means are determined through linear interpolation to provide that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure, according to the HVL provisions of 1020.30(m)(1).</p>
SE-# 7	<p>IEC 60601-2-7 is withdrawn and replaced with IEC 60601-1 3rd Ed.</p>

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 EPX mobile X-ray series 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 similar or higher than that of the predicate device such as the X-ray generator and X-ray tube anode heat content (Heating Unit).

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 is substantially equivalent to the predicate device in terms of safety and effectiveness.

10. Description of non-clinical tests.

EPX series diagnostic X-ray system has been tested for electrical safety and electromagnetic compatibility (IEC 60601-1-2, IEC , IEC 60601-2-54, IEC 60601-1-3, IEC 60601-2-28, and IEC 60601-1:2005.) The device also complies with FDA EPRC Performance Standard: 21 CFR 1020.30 and 31. The software validation and verification testing was also performed. The results of nonclinical testing indicate that the EPX series mobile X-ray system is as safe and effective as the predicate device.

Compliance evidences were submitted for the following standards:

- IEC 60601-1: Test Report issued by 3rd party testing lab
- IEC 60601-1-2: Test Report issued by 3rd party testing lab
- IEC 60601-1-3: Test Report issued by 3rd party testing lab
- IEC 60601-2-54: Test Report issued by 3rd party testing lab
- EPRC Standard: 21 CFR 1020.30 and 31: In-house Test Report
- ISO 14971: Risk management file

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.



EPX Series Diagnostic X-ray System:
F1600, F2400, F2800, F3200, F4000, F5000

12. Conclusion as to Substantial Equivalence

EPX SERIES are substantially equivalent to the predicate device PORTA 100 HF (K122697). These 2 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, ECOTRON CO., LTD. concludes EPX series of mobile X-ray system are substantially equivalent with the predicate device PORTA 100 HF (K122697) of JOB Corporation.