December 20, 2022

POSKOM Co.,Ltd.
% Bokyeong Kim
Senior Researcher
GMS Consulting
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Seoul, Mapo-gu 03909
SOUTH KOREA

Re: K222896
Trade/Device Name: AirRay
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: September 19, 2022
Received: September 23, 2022

Dear Mr. Bokyeong 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang
2022.12.20
12:19:52
-05'00'

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices
and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222896

Device Name
AirRay

Indications for Use *(Describe)*
The POSKOM Portable X-ray unit is a device that can conveniently generate X-rays for diagnosis when the patient condition is difficult to move. Mainly used by trained specialists, doctors or radiologists.

Indication:
The POSKOM Battery Type Portable X-ray Unit is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the body parts.
The device must be used for stand mounted diagnostic imaging of head, abdomen, or extremities.
The device must be used for stand mounted imaging of the chest.
Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Contraindication:
The use of X-radiation for diagnostic purposes in the following subjects is contraindicated.
- Pregnancy, especially first trimester

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.

5. 510(K) Summary

510(k) Summary

[As Required by 21 CFR 807.92]

[510(k) Number: K222896]

1. Date Prepared [21 CFR 807.92(a)(a)]

September 19, 2022

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: POSKOM Co., Ltd.
- Address: POSKOM Tower, 227 Sowon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, 10534, Republic of Korea
- Contact Name: Jong Rae Park / President
- Telephone No.: +82–31–906–9007
- Email Address: jerryhana@poskom.com
- Registration No.: 892.1720

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Type Name	AirRay-20H, AirRay-20HL, AirRay-20HW, AirRay-20HLW
Product Name	Diagnostic X-ray Unit
Model Name	AirRay
Regulation Number	21CFR892.1720
Regulation Name	Mobile X-Ray System
Regulation Class	II
Product Code	IZL
510(k) Review Panel	Radiology

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

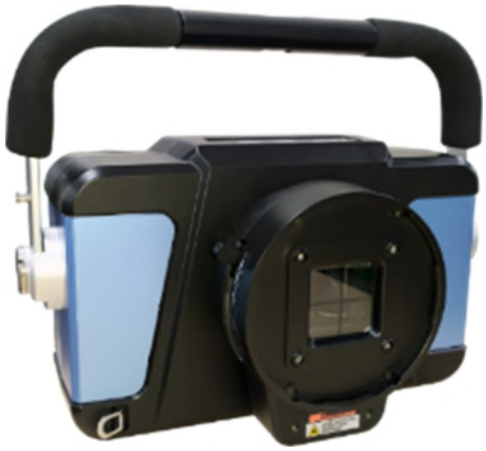
Predicate Device#1

- 510(k) Number: K182207
- Applicant: MinXray., Inc
- Trade/Device Name: TR90BH
- Regulation Name: Mobile x-ray system
- Regulation Number: 21 CFR 892.1720
- Classification Product Code: IZL
- Device Class: II
- 510(k) Review Panel: Radiology

These predicate devices have not been subject to a design-related recall

5. Description of the Device [21 CFR 807.92(a)(4)]

The device is intended to assist the diagnosis of bones and tissues through X-ray exposure using an imaging receptor. The image receptor (an integral part of a complete diagnostic system) is not part of this submission.



5.1 Types of AirRay and differences

Model name	Difference			
	Use environment	Skin guard	Dual Laser	Wireless charge
AirRay-20H	Human	O	X	X
AirRay-20HL	Human	O	O	X
AirRay-20HW	Human	O	X	O
AirRay-20HLW	Human	O	O	O

5.2 AirRay components

Component	Picture
1. Main Body (with skin guard)	
2. Battery (2EA)	
3. Remote Controller (Optional)	

4. Power cable (1.5m) and Adaptor	
5. Hand switch	
6. Carrying Case (with key and shoulder strap)	
7. User Manual	

5.3 Device software (firmware)

5.3.1 Role of S/W

The primary function of the software is the operation of X-ray equipment for image acquisition. The user operates the X-ray Operation Unit to control the X-ray Control Unit. In X-ray Operation Unit, user can use Power On / Off, X-ray setting, irradiation, and options of X-ray Control Unit. The X-ray control unit carries out the X-ray setting and irradiation with the information transmitted from the X-ray operation

5.3.2 Revision Level History

MCU Firmware

Version	Description of changes	Date
U1.00	First Release	2022.06.14
U1.01	Add function of Password ON/OFF and Changed Password	2022.10.20

Charger Firmware

Version	Description of changes	Date
C1.00	First Release	2022.06.14

5.3.3 Operational Environment

MCU firmware

- Version: U1.00
- Control of parameters to be used for acquiring the images
- Controlling Generator

MCU Board

Micom

- Vender: ST
- Model: STM32F103VCT6

Flash Memory

- Vender: ST
- Model: SST25VF020B

Charger firmware

- Version: C1.00
- Charging voltage control

Charger Interface Board

Micom

- Vender: ST
- Model: STM32F103RCT6

6. Indications for use [21 CFR 807.92(a)(5)]

The POSKOM Portable X-ray unit is a device that can conveniently generate X-rays for diagnosis when the patient condition is difficult to move. Mainly used by trained specialists, doctors or radiologists.

Indication:

The POSKOM Battery Type Portable X-ray Unit is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the body parts.

The device must be used for stand mounted diagnostic imaging of head, abdomen, or extremities.

The device must be used for stand mounted imaging of the chest.

Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Contraindication:

The use of X-radiation for diagnostic purposes in the following subjects is contraindicated.

- Pregnancy, especially first trimester

7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6)]

Summary of technological characteristics of the device compared to the predicate device. [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of these devices compared to the predicate device which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the AirRay and the predicate device:

[Table 1. Comparison of Proposed Device to Predicate Devices]

	Proposed Device	Predicate Device	
K Number	-	K182207	
Manufacturer	POSKOM Co., Ltd.	MinXray., Inc.	
Trade Name	AirRay	TR90BH	
Device Classification Name	Mobile x-ray system	Mobile x-ray system	Same
Product Code	IZL	IZL	Same
Regulation Number	21CFR892.1720	21CFR892.1720	Same
510(k) Review Panel	Radiology	Radiology	Same
Intended Use	The POSKOM Portable X-ray unit is a device that can conveniently generate X-rays for diagnosis when the patient condition is difficult to move. Mainly used by trained specialists, doctors or radiologists. Indication: The POSKOM Battery Type Portable X-ray Unit is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the body parts. The device must be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device must be used for stand mounted imaging of the chest.	The TR90BH is a portable X-ray system with following limitations of use: The device may be used for handheld diagnostic imaging of body extremities. The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest when used without a grid. - Not to be used on bariatric patients, unless imaging body extremities - Not for mammography use - The TR90BH is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.	Similar

	Proposed Device	Predicate Device	
	Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Contraindication: The use of X-radiation for diagnostic purposes in the following subjects is contraindicated. - Pregnancy, especially first trimester		
Principle of Operation	General Purpose Diagnostic X ray	General Purpose Diagnostic X ray	Same
Size	325 X 268 X 250 mm	219 x 442 x 190 mm	Similar
Weight	5.0kg	7.5kg	Similar
Energy source	Lithium Polymer Battery 3.7V 5000mAh	Lithium-ion Rechargeable Battery (57.6DC), 300 exposures per charge.	Similar
Exposure times	0.02 sec – 2 sec	0.01 sec – 1.0 sec : 0.01 sec Step High Power Mode 0.01 sec – 0.3 sec : 0.01 sec Step	Similar
Tube current [mA]	20mA (50 ~ 80kV / 0.4 ~ 3.2mAs) 10mA (50 ~ 70kV / 3.6 ~ 20mAs) 10mA (71 ~ 80kV / 3.6 ~ 16mAs) 15mA (81 ~ 90kV / 0.4 ~ 3.2mAs) 8mA (81 ~ 90kV / 3.6 ~ 16mAs)	20 mA @ 40 kVDC – 60 kVDC (2 kVP steps) 15 mA @ 62 kVDC – 80 kVDC (2 kVP steps) 10 mA @ 82 kVDC – 90 kVDC (2 kVP steps) High Power Mode 15 mA @ 82 kVDC – 90 kVDC (2 kVP steps) Comment: 90 kVP maximum instead of 120 kVP maximum.	Similar
Tube Voltage Range [kVp]	50 - 90kVp	40 - 90kVp	Similar
Memory settings	10 Memories	10 memories	Same
HF Generator	High frequency	High frequency	Same
Output power [kW]	1.6kW	1.35 kW	Similar
X-ray Tube	OX/70-1.0 (C.E.I.)	D-0814	Different
Collimator	Double slit type and manually operation with LED Light indicator	Mikasa BLD34L	Different
Performance standard	IEC 60601-1-3:2008 +AMD:2013	IEC 60601-1-3:2008 IEC 60601-2-28:2010	Similar

	Proposed Device	Predicate Device	
	IEC 60601-2-28:2017 IEC 60601-2-54:2009 +AMD2:2018	IEC 60601-2-54:2009	
Electrical safety	IEC 60601-1:2005 +AMD1:2012 IEC 60601-1-2:2014 IEC 60601-1-3:2008 +AMD:2013 IEC 60601-1-6:2010 +AMD1:2013 IEC 62304: 2006 IEC 62366:2007 +AMD1:2014	IEC 60601-1:2012 IEC 60601-1-2:2007 IEC 60601-1-6:2010 IEC 62304:2006 IEC 62366:2007	Similar

The table also provides rationale for a little difference in support of substantial equivalence to the predicate devices.

Justification to Support Substantial Equivalence
AirRay is hardly different from the TR90BH except for Collimator and X-ray Tube. But the above differences are inherent characteristics of device. The most important tube current and tube voltage range are similar to predicate device. And Size, Weight, Energy source, Exposure times, Performance standard, Electrical safety are also similar to predicate devices, but they are not items that significantly affect performance, and their intended use is equivalent. The proposed device, AirRay has been tested about electrical safety, EMC and software has been validated.

8. Non-Clinical Test summary

The AirRay complies with voluntary standards for electrical safety, electromagnetic compatibility.

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

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The AirRay complies with the electrical safety and electromagnetic compatibility requirements established by the standards.

- IEC 60601-1:2005/AM1:2012 Medical electrical equipment - Part 1: General requirement for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part1-2: General requirements Section1.2 Collateral standard: Electromagnetic compatibility
- IEC 60601-1-3:2008 Medical electrical equipment Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-Ray equipment

- IEC 60601-2-54:2009/AM2:2018 Medical electrical equipment Part 2-54: Particular requirements for the basic safety and essential performance of X-Ray equipment for radiography and radioscopy

2) Software Validation

The AirRay contain MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated.

Software information is provided in accordance with FDA guidance:

- "The content of premarket submissions for software contained in medical devices, on May 11, 2005"
- IEC 62304:2006 (First Edition) Medical device software: Software life-cycle processes

Rechargeable Li-ion polymer battery pack has been tested and is in conformity with the standard IEC 62133. And we performed the battery performance test about battery charging time, discharge time and usage count, Battery rated load, overcurrent protection and recovery.

Furthermore, the following Specific Guidance Document was utilized in the device development to ensure the safety of this device for both the operators and patients:

"Radiation Safety Consideration for X-ray Equipment Designed for Hand-Held Use"

The device also conforms to the following:
21 CFR 1020 Subchapter J: Performance Standards for Ionizing Radiation Emitting Products
21 CFR 1020.30: Diagnostic x-ray system and their major components
21 CFR 1020.31: Radiographic Equipment

9. Conclusion [21 CFR 807.92(b)(3)]

The AirRay has similar intended use and technical characteristics to the predicate device. Based on this information, we conclude that the differences between the proposed device and predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness.