February 23, 2026

Poskom Co., Ltd.
℅ Seong Jeong Hyun
Manager
Poskom Tower, 227, Sowon-Ro Deogyang-Gu, Goyang-Si
Gyeonggi-Do, 10534
REPUBLIC OF KOREA

Re: K253244
Trade/Device Name: AirRay-mini 80A, AirRay-mini 90A, AirRay-mini 80F, AirRay-mini 90F (AirRay-mini)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: January 22, 2026
Received: January 22, 2026

Dear Seong Jeong Hyun:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253244

Please provide the device trade name(s).

AirRay-mini 80A, AirRay-mini 90A, AirRay-mini 80F, AirRay-mini 90F (AirRay-mini)

Please provide your Indications for Use below.

The AirRay-mini is a handheld, portable X-ray generator.
This device is intended for use by qualified and trained healthcare professionals on adult patients to produce diagnostic X-ray images of the extremities.
This device is not intended for mammography.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

[As Required by 21 CFR 807.92]

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

02.07.2025

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: Jeong Hyun, Sung
- Telephone No.: +82 31-906-9007
- Email Address: jerryhana@poskom.com
- Registration No.: K253244

3. Identification of Proposed Device(s) [21 CFR 807.92(a)(2)]

510(k) Number	K253244
Trade/Device/Model Name	AirRay-mini 80A, AirRay-mini 90A, AirRay-mini 80F, AirRay-mini 90F(AirRay-mini)
Product Name	AirRay-mini
Common Name	Mobile x-ray unit
Regulation Name	Mobile x-ray system.
Regulation Number	21 CFR 892.1720
Classification Product Code	IZL
Device Class	II
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;

510(k) Number	K143494
Trade/Device/Model Name	ADX6000
Product Name	ADX6000
Common Name	Mobile x-ray system
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 AirRay-mini is a portable, battery-powered X-ray generator intended to provide controlled X-ray radiation for use with separately cleared solid-state detectors or digital radiography systems. The device consists of an X-ray control unit, a high-voltage generator, an X-ray tube assembly, a hand switch, and associated electronics.

DC power from the internal battery is supplied to the inverter, which generates a high-voltage output applied across the X-ray tube. Electrons emitted from the cathode are accelerated toward the anode target, where their deceleration produces X-ray radiation. The device delivers X-rays according to user-selected parameters such as tube voltage (kV), tube current (mA), and exposure time (mAs).

The AirRay-mini does not include an image receptor and does not acquire or process diagnostic images. Diagnostic image formation and quality depend entirely on the separately paired imaging system.

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

The AirRay-mini is a handheld, portable X-ray generator.
This device is intended for use by qualified and trained healthcare professionals on adult patients to produce diagnostic X-ray images of the extremities.
This device is not intended for mammography.

7. Technological Characteristics (Equivalence to 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-mini and the predicate device:

[Table 3. Comparison of Proposed Device to Predicate Devices]

	Proposed Device		**Predicate Device**	**Note**
K Number	K253244		K143494	-
Manufacturer	POSKOM		DEXCOWIN	-
Trade Name	AirRay-mini 90A/90F	AirRay-mini 80A/80F	ADX6000	-
Product Name	AirRay-mini		ADX6000	-
Product Code	IZL		IZL	Identical
Regulation Number	21 CFR 892.1720		21 CFR 892.1720	Identical
510(k) Review Panel	RADIOLOGY		RADIOLOGY	Identical
Indications for Use	The AirRay-mini is a handheld, portable X-ray generator. This device is intended for use by qualified and trained healthcare professionals on adult patients to produce diagnostic X-ray images of the extremities. This device is not intended for mammography.		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.	Identical
Configuration	Portable		Portable	Identical
Generator Type	Inverter		Inverter	Identical
Max Power Output	500W	420W	400 kW	Similar
Peak Voltage	90kV	80kV	80 kV	Similar
Tube Current	5-10mA	5-8mA	1-5mA	Similar
Tube Current	5-10mA	5-8mA		Similar

	Proposed Device		Predicate Device	Note
Total Filtration	2.5 mm AL	2.7 mm AL	2.5 mm AL	Identical
Power Source	AC Line, DC Battery 100-240V AC, DC 22.2-25.2V		AC Line, DC Battery 100-220V AC, DC 18.5-21V	Identical
Electrical Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-54		IEC-60601-1 IEC-60601-1-2, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28	Similar
Photos				Similar
Weight	3.5 kg		3.6 kg	Similar

The AirRay-mini is substantially equivalent to its predicate device, the ADX6000, in design concept, technological characteristics, and intended use. Both devices are portable X-ray generators intended for use by qualified healthcare professionals in professional healthcare environments and are limited to taking diagnostic X-ray exposures of extremities when used in conjunction with separately cleared solid-state detectors or digital radiography systems. Neither device includes an image receptor, and diagnostic image quality is determined solely by the paired imaging system.

The electrical safety, EMC, and performance characteristics of the AirRay-mini have been evaluated in accordance with applicable standards, and the software has been validated. The overall output characteristics—including peak voltage, tube current ranges, exposure parameters, and dose output—are comparable to those of the predicate device. These similarities demonstrate that the technological characteristics do not introduce new performance concerns.

The primary difference between the AirRay-mini and the predicate device lies in product design, including form factor and mechanical configuration. These differences do not affect the device's essential performance or risk profile, as confirmed through testing and risk management activities. No new or different questions of safety or effectiveness are introduced as a result of these design differences.

Therefore, the AirRay-mini is substantially equivalent to the ADX6000.

8. Non-Clinical Test Summary

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

Standards No.	Standards Organization	Standard Title	Version	Publication Year
60601-1	IEC	Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance	3.2	2020
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	4.1	2020
60601-2-28	IEC	Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	3.0	2017
60601-2-54	IEC	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	2.0	2022

2) Software Validation

The 'AirRay-mini' contains software with a Basic Documentation Level. 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:

- Content of Premarket Submissions for Device Software Functions (June 14, 2023)

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between the proposed device and the predicate device, K143494 that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

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

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that the 'AirRay-mini' is substantially equivalent in safety and effectiveness to the predicate device as described herein.