December 19, 2025

Poskom Co., Ltd.
% Jonghyeon Kim
CEO
GMSC Co., Ltd.
B 612, 66, Cheongcho-Ro, Deokyang-Gu, Goyang-Si
Gyeonggi-Do, 10543
REPUBLIC OF KOREA

Re: K250976
Trade/Device Name: Airbile-100
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: November 14, 2025
Received: November 14, 2025

Dear Jonghyeon 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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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 Radiologic 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250976

Device Name
Airbile-100

Indications for Use *(Describe)*

The Airbile-100 Mobile 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 skull, spinal column, chest, abdomen, extremities, and other body parts.
Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Attachment U-03

510(k) Summary

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.: K250976

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

510(k) Number	K250976
Trade/Device/Model Name	Airbile-100
Product Name	Airbile-100
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 DEVICES

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	K182317
Trade/Device/Model Name	AMADEO M-DR mini
Product Name	AMADEO M-DR mini
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 'Airbile-100' is a battery-powered mobile X-ray imaging device mainly used for hospital rounds and consists of an X-ray control unit, a high-voltage generator, an X-ray tube unit, a hand switch, etc. Inverter X-ray high-voltage device, electrons are generated from the tungsten filament on the cathode side of the X-ray tube. DC power is supplied to the inverter by a battery, and a high-frequency, stable, high-voltage DC output voltage with an amplified high frequency is applied between the cathode and anode, so that the generated electrons move at high speed due to the voltage difference and are slowed down by striking the target material on the anode, and the energy is converted, and the X-rays generated by the energy conversion are passed to the human body parts for the necessary diagnosis of the patient. It is a device that can generate X-rays according to the set values such as supply voltage, supply current, and irradiation time and take pictures for the necessary diagnosis of the patient.

Additionally, it should be noted that the Airbile-100 does not include the X-ray detector. For image acquisition, an external X-ray detector must be used in combination with this device.

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

The Airbile-100 Mobile 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 skull, spinal column, chest, abdomen, extremities, and other body parts.

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

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 Airbile-100 and the predicate device:

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

	Proposed Device	Predicate Device	Note
K Number	K250976	K182317	-
Manufacturer	POSKOM	OR Technology	-
Trade Name	Airbile-100	AMADEO M-DR mini	-
Product Name	Airbile-100	AMADEO M-DR mini	-
Product Code	IZL	IZL	
Regulation Number	21 CFR 892.1720	21 CFR 892.1720	
510(k) Review Panel	RADIOLOGY DEVICES	RADIOLOGY DEVICES	
Indications for Use	The Airbile-100 Mobile 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 skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	These Portable Diagnostic Radiographic Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography).	Identical
Configuration	Line operated portable	Line operated portable	Identical
Generator	High frequency made by POSKOM	High frequency made by POSKOM	Identical
Generator power	5 kW	5 kW	Identical
Peak Voltage	120 kV	110 kV	Similar

	Proposed Device	Predicate Device	Note
Current	100 mA	100 mA	Identical
Max. Exposure time	0.1 ~ 100 mAs	0.4 ~ 100 mAs	Similar
Collimator	MCM-100BTL	POSKOM PCMAX-100CAH	Similar
Software	Micom	DICOMPACS DX-R	Similar
Connections	Hand Switch	Ethernet or Wi-Fi	Different
Power Source	AC Line	AC Line	Identical
Electrical Safety	IEC 60601-1: 2005+AMD1:2012+AMD2:2020 IEC 60601-1-2: 2014+AMD1:2020 IEC 60601-1-3: 2008+AMD1:2013+AMD2:2021 IEC 60601-1-6: 2010+AMD1:2013+AMD2:2020 IEC 60601-2-54: 2022	Electrical Safety per IEC-60601. EMC per IEC-60601-1-2; IEC 60601-1-3 Radiation protection in diagnostic X-ray equipment IEC 60601-2-54 Particular Requirements for The Basic Safety And Essential Performance of X-ray Equipment for Radiography and Radioscopy	Similar
Photos			

The Airbile-100 is substantially equivalent to its predicate device, the AMADEO M-DR mini, in design concept, function, and intended use. The proposed device has completed electrical safety, EMC, and performance testing, and its software has been validated.

Both devices share the same indications for use, product code, regulation number, and 510(k) review panel. Key technical characteristics—including output power, generator type, operating frequency, tube current, and maximum exposure time—are comparable and do not introduce new risks or impact performance.

One distinction is the type of connection interface implemented in each device.

The Airbile-100 includes a simple wired connection dedicated solely to the hand switch, whereas the predicate device includes Ethernet and/or Wi-Fi interfaces for system communication. Although both devices contain a connection interface, the type, function, and technological implementation differ. This difference does not affect the safety or effectiveness of the proposed device because the Airbile-100 operates as a stand-alone X-ray generator without any network-based communication.

Therefore, these differences do not raise different questions of safety or effectiveness compared to the predicate device.

8. Non-Clinical Test Summary

The 'Airbile-100' 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 'Airbile-100' 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 'Airbile-100' contains 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 June 14, 2023

3) Bench Testing

The Airbile-100 mobile X-ray unit underwent comprehensive non-clinical performance testing to evaluate its imaging quality in accordance with IEC 62220-1-1 standards. Key parameters assessed included Modulation Transfer Function (MTF), Detective Quantum Efficiency (DQE), Noise Power Spectrum (NPS), detector linearity, and maximum spatial resolution (lp/mm).

Testing was conducted using the Airbile-100 equipped with a flat panel detector under standardized conditions with calibrated instrumentation and imaging phantoms. The MTF was measured by the slanted-edge method at a 2.8 μGy exposure, and DQE was evaluated over relevant spatial frequencies.

Results demonstrate that the device maintains stable and consistent imaging performance, meeting or exceeding the diagnostic quality requirements for general radiography. The detector response was linear over applicable exposure ranges, and maximum resolution measurements aligned with design specifications.

These results support the substantial equivalence of the Airbile-100 to the predicate device in terms of imaging performance and safety for its intended use.

4) Cybersecurity Testing Justification

The subject device, Airbile-100, does not connect to the internet and lacks any active access ports, making it inherently protected from network-based cyber threats. The device's firmware operates on a microcontroller without an operating system or network stack, and no communication-capable IC chips are installed. Firmware updates require physical access to the internal console board with specialized tools unavailable to users, preventing unauthorized tampering or software modification. The infrared remote control operates via a limited-range, line-of-sight signal with no power on/off control capability, further minimizing cybersecurity risks. Additionally, the device does not store or transmit any patient data. Due to these architectural and operational factors, the Airbile-100 is not a cyber device, and cybersecurity testing is not necessary for this product.

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, K182317 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 'Airbile-100' is substantially equivalent in safety and effectiveness to the predicate device as described herein.