

K250976 Airbile-100Dec 19, 2025
263 days to decisionK250976 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k250976/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Mar 31, 2025
Decision date	Dec 19, 2025
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Poskom Co., Ltd.
Location	Gyeonggi-Do, KR
Contact	Seong Jeong Hyun
510(k) history	3 submissions · 3 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	GMSC Co., Ltd.
Contact	Jonghyeon Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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