

K243864 BONX805Sep 12, 2025
269 days to decisionK243864 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k243864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Dec 17, 2024
Decision date	Sep 12, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bontech Co., Ltd.
Location	Suwon-Si, KR
Contact	Ki-Chan An
510(k) history	2 submissions · 2 cleared · 2020-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243864/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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