

K251223 HnX-P1, HnX-PBAug 4, 2025
105 days to decisionK251223 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k251223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Apr 21, 2025
Decision date	Aug 4, 2025
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	H&abyz Co., Ltd.
Location	Yongin-Si, KR
Contact	Jimin Han
510(k) history	4 submissions · 4 cleared · 2021-2025

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