

K250597 REMEX Xcam6Jul 31, 2025
153 days to decisionK250597 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k250597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Feb 28, 2025
Decision date	Jul 31, 2025
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Remedi, Inc.
Location	Seoul, KR
Contact	Seong-Geun Park
510(k) history	1 submissions · 1 cleared · 2025-2025

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