

K251443 PROMOAug 22, 2025
105 days to decisionK251443 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k251443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	May 9, 2025
Decision date	Aug 22, 2025
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	DRGEM Corporation
Location	Echo, OR, US
Contact	Doonam Choi
510(k) history	13 submissions · 13 cleared · 2010-2025

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