

K242015 TOPAZ Mobile X-ray System (Models : TOPAZ-32D, TOPAZ-40D)Dec 16, 2024
159 days to decisionK242015 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k242015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Jul 10, 2024
Decision date	Dec 16, 2024
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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