

**K260085 RAYMO Mobile X-ray System (Model: RAYMO)**May 14, 2026  
122 days to decisionK260085 · Product code: **IZL** · Radiology  
Source: <https://www.510kdatabase.net/k260085/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Jan 12, 2026
Decision date	May 14, 2026
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DRGEM Corporation</b>
Location	Echo, OR, US
Contact	Yubin CHO
510(k) history	14 submissions · 14 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260085/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 9, 2026