

**K201124 TOPAZ Mobile DR System**May 19, 2020  
22 days to decisionK201124 · Product code: **IZL** · Radiology  
Source: <https://www.510kdatabase.net/k201124/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Mobile (IZL)
Date received	Apr 27, 2020
Decision date	May 19, 2020
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DRGEM Corporation</b>
Location	Echo, OR, US
Contact	Ki-Nam Yang
510(k) history	13 submissions · 13 cleared · 2010-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201124/> 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 May 26, 2026