

**K241350 Clarify DL**Jan 3, 2025  
235 days to decisionK241350 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k241350/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 13, 2024
Decision date	Jan 3, 2025
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Medical Systems Israel, Functional Imaging</b>
Location	Tirat Hacarmel, IL
Contact	Mousa Elias Maysana
510(k) history	4 submissions · 4 cleared · 2010-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>GE Healthcare</b>
Contact	Maysana Mousa Elias

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241350/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026