FDA 510(k) Premarket Notification

K241350 Clarify DL

CLEARED

Jan 3, 2025
235 days to decision

K241350 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k241350/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**GE Healthcare**
Contact	Maysana Mousa Elias

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov