

K253639 ViewJan 8, 2026
50 days to decisionK253639 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k253639/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 19, 2025
Decision date	Jan 8, 2026
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare
Location	Waukesha, WI, US
Contact	Tong Zhao
Website	http://www3.gehealthcare.com/en
510(k) history	168 submissions · 168 cleared · 2004-2026

GE HealthCare is an American multinational medical technology company headquartered in Waukesha, US. The company operates globally across medical imaging, ultrasound, patient care solutions, and pharmaceutical diagnostics. GE HealthCare has received FDA 510(k) clearances from total submissions since 2004. Radiology devices represent the dominant focus, accounting for 73% of regulatory submissions. The company's latest FDA 510(k) clearance was in 2026, reflecting continued innovation in medical imaging technologies. Recent cleared devices span Radiology specialties includi...