

**K211312 Universal Viewer**May 21, 2021  
21 days to decisionK211312 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k211312/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 30, 2021
Decision date	May 21, 2021
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Healthcare</b>
Location	Waukesha, WI, US
Contact	John Braam
Website	<a href="http://www3.gehealthcare.com/en">http://www3.gehealthcare.com/en</a>
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...