

**K121019 OPTIMA NM/CT 640**Apr 19, 2012  
15 days to decisionK121019 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k121019/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Apr 4, 2012
Decision date	Apr 19, 2012
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Healthcare</b>
Location	Waukesha, WI, US
Contact	ELI WERNER
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...

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