

**K122921 C1-6-D ULTRASOUND TRANSDUCER**Oct 5, 2012  
11 days to decisionK122921 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k122921/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Sep 24, 2012
Decision date	Oct 5, 2012
Days to decision	11 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Healthcare</b>
Location	Waukesha, WI, US
Contact	BRYAN BEHN
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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