

**K052167 DATEX-OHMEDA S/5 TONOMETRY MODULE, E TONO  
AND ACCESSORIES**Sep 8, 2005  
30 days to decisionK052167 · Product code: **CCK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k052167/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Aug 9, 2005
Decision date	Sep 8, 2005
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Healthcare</b>
Location	Waukesha, WI, US
Contact	JOEL C KENT
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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