

**K110287 PHILIPS ECG LEADWIRE SET**Feb 15, 2011  
15 days to decisionK110287 · Product code: **DSA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k110287/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Cable, Transducer And Electrode, Patient, (including Connector) (DSA)
Date received	Jan 31, 2011
Decision date	Feb 15, 2011
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Medical Systems</b>
Location	Seattle, WA, US
Contact	PETER SCHIPELLITI
510(k) history	107 submissions · 105 cleared · 2002-2021

Philips Medical Systems is a Dutch multinational health technology company headquartered in Amsterdam with U.S. operations based in Seattle. The company evolved from a consumer electronics conglomerate founded in 1891 to a healthcare-focused organization. Philips Medical Systems has received FDA 510(k) clearances from total submissions between 2002 and 2021. The company's regulatory focus centered on Cardiovascular devices, which represented 79% of all submissions. This historical record reflects the company's significant presence in diagnostic ultrasound systems and pati...

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