

**K031422 PHILIPS PAGE WRITER TRIM SERIES CARDIOGRAPH  
INCLUDING I, II, III, MODELS 860286, 860287, 860288, 860289,  
860290, 860291**Jul 3, 2003  
58 days to decisionK031422 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k031422/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Electrocardiograph (DPS)
Date received	May 6, 2003
Decision date	Jul 3, 2003
Days to decision	58 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Medical Systems</b>
Location	Seattle, WA, US
Contact	SONGHUA ZHANG
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...