

**K032103 PHILIPS TRACEMASTER ECG MANAGEMENT SYSTEM, MODELS M5100A AND M5101A**Jul 22, 2003  
14 days to decisionK032103 · Product code: **DSH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k032103/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Jul 8, 2003
Decision date	Jul 22, 2003
Days to decision	14 days
Third-party review	No
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...

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