

**K013425 HEARTSTREAM/HEARTSTART FR2 AED ECG CABLE,  
MODELS M3860A, M3861A, M3840A, M3841A**Jan 14, 2002  
90 days to decisionK013425 · Product code: **MKJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k013425/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Oct 16, 2001
Decision date	Jan 14, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Medical Systems</b>
Location	Seattle, WA, US
Contact	TAMARA YOUNT
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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Device record: <https://www.510kdatabase.net/k013425/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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