

K031187 HEARTSTART MRX, MODEL M3535AAug 27, 2003
134 days to decisionK031187 · Product code: **MKJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k031187/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Apr 15, 2003
Decision date	Aug 27, 2003
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems
Location	Seattle, WA, US
Contact	PETER OHANIAN
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...
