FDA 510(k) Premarket Notification

CLEARED

K063375 HEARTSTART MRX, MODELS M3535A OR M3536A

Jan 11, 2007
64 days to decision

K063375 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k063375/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Nov 8, 2006
Decision date	Jan 11, 2007
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems**
Location	Seattle, WA, US
Contact	DENISE HALEY
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...