FDA 510(k) Premarket Notification

CLEARED

K014157 HEARTSTREAMFR2 AED WITH M3848A AND M3849A, MODELS M3860A, M3861, M3840A, M3841A

Jan 17, 2002
29 days to decision

K014157 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k014157/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Special
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Dec 19, 2001
Decision date	Jan 17, 2002
Days to decision	29 days
Third-party review	No

APPLICANT

Company	**Philips Medical Systems**
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...