FDA 510(k) Premarket Notification

CLEARED

K030417 DISPOSABLE STERILE INTERNAL DEFIBRILLATION PADDLES (SWITCHED-LARGE), DISPOSABLE STERILE INTERNAL DEFIBRILLATION PADDLES

May 9, 2003
88 days to decision

K030417 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k030417/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Feb 10, 2003
Decision date	May 9, 2003
Days to decision	88 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...