FDA 510(k) Premarket Notification

K871135 HEARTSTART 2000, MANUAL MEDICAL CONTROL MODULE

CLEARED

May 12, 1987
53 days to decision

K871135 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k871135/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Mar 20, 1987
Decision date	May 12, 1987
Days to decision	53 days
Third-party review	No

APPLICANT

Company	**First Medical Devices Corp.**
Location	Bellevue, WA, US
Contact	BRUCE G HAGGER
510(k) history	7 submissions · 7 cleared · 1986-1990