FDA 510(k) Premarket Notification

K860676 HEARTSTART 2000

CLEARED

Apr 30, 1986
64 days to decision

K860676 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k860676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Feb 25, 1986
Decision date	Apr 30, 1986
Days to decision	64 days
Third-party review	No

APPLICANT

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