FDA 510(k) Premarket Notification

K893990 P POLYMER

CLEARED

Oct 12, 1989
129 days to decision

K893990 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k893990/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Jun 5, 1989
Decision date	Oct 12, 1989
Days to decision	129 days
Third-party review	No

APPLICANT

Company	**Pace West**
Location	Fairfield, CA, US
Contact	BRENT BOWEN
510(k) history	1 submissions · 1 cleared · 1989-1989