FDA 510(k) Premarket Notification

K895113 COORDINATOR

CLEARED

Oct 26, 1989
72 days to decision

K895113 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k895113/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Aug 15, 1989
Decision date	Oct 26, 1989
Days to decision	72 days
Third-party review	No

APPLICANT

Company	**Cardiotronics, Inc.**
Location	West Carlsbad, CA, US
Contact	TIM WAY
510(k) history	27 submissions · 27 cleared · 1988-1995