

K895113 COORDINATOROct 26, 1989
72 days to decisionK895113 · Product code: **LDD** · CardiovascularSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k895113/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 6, 2026