

K880936 TRIAD-EPJul 18, 1988
133 days to decisionK880936 · Product code: **DRO** · Cardiovascular
Source: <https://www.510kdatabase.net/k880936/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Mar 7, 1988
Decision date	Jul 18, 1988
Days to decision	133 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k880936/>; 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 1, 2026