FDA 510(k) Premarket Notification

K964469 700-F SERIES STIMULATION ELECTRODES

CLEARED

Dec 11, 1996
34 days to decision

K964469 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k964469/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Nov 7, 1996
Decision date	Dec 11, 1996
Days to decision	34 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Cardiotronics Systems, Inc.**
Location	Carlsbad, CA, US
Contact	TIM J WAY
510(k) history	4 submissions · 4 cleared · 1996-1997