FDA 510(k) Premarket Notification

K912621 MODEL #911 STEALTH MULTI PADS

CLEARED

Oct 16, 1991
125 days to decision

K912621 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k912621/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Jun 13, 1991
Decision date	Oct 16, 1991
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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