FDA 510(k) Premarket Notification

K884530 TRIAD-EP II, PLATE INPUT

CLEARED

Nov 17, 1988
20 days to decision

K884530 · Product code: **DRO** · Cardiovascular
Source: https://www.510kdatabase.net/k884530/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Oct 28, 1988
Decision date	Nov 17, 1988
Days to decision	20 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