FDA 510(k) Premarket Notification

K872778 PACESTART

CLEARED

Nov 4, 1987
113 days to decision

K872778 · Product code: **DRO** · Cardiovascular
Source: https://www.510kdatabase.net/k872778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Jul 14, 1987
Decision date	Nov 4, 1987
Days to decision	113 days
Third-party review	No

APPLICANT

Company	**Pacific Rim Engineering & Mfg.**
Location	Carlsbad, CA, US
Contact	TIM J WAY
510(k) history	1 submissions · 1 cleared · 1987-1987