

K915632 PACEART CPTS-86/12Apr 14, 1992
119 days to decisionK915632 · Product code: **KRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k915632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function, Indirect (KRE)
Date received	Dec 17, 1991
Decision date	Apr 14, 1992
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Paceart, Inc.
Location	Millburn, NJ, US
Contact	MICHAEL BERGELSON
510(k) history	9 submissions · 9 cleared · 1987-2001

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