

K870909 PACEMAKER FUNCTION ANALYZERApr 27, 1987
53 days to decisionK870909 · Product code: **KRE** · CardiovascularSource: <https://www.510kdatabase.net/k870909/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function, Indirect (KRE)
Date received	Mar 5, 1987
Decision date	Apr 27, 1987
Days to decision	53 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k870909/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 3, 2026