

K110693 PACEART OPTIMA SYSTEM SOFTWAREJun 8, 2011
89 days to decisionK110693 · Product code: **KRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k110693/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function, Indirect (KRE)
Date received	Mar 11, 2011
Decision date	Jun 8, 2011
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	RACHEL U LIBI
Website	https://www.medtronic.com
510(k) history	209 submissions · 208 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...

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