FDA 510(k) Premarket Notification

K024278 PACEART SYSTEM

CLEARED

May 29, 2003
157 days to decision

K024278 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k024278/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Dec 23, 2002
Decision date	May 29, 2003
Days to decision	157 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Vascular**
Location	Walker, MI, US
Contact	KAREN RUTH-JARMON
510(k) history	475 submissions · 453 cleared · 1977-2023