FDA 510(k) Premarket Notification

K880283 PACEART PACEMAKER PATIENT TEST SYST/TEL OPT CPTS

CLEARED

Mar 9, 1988
47 days to decision

K880283 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k880283/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Jan 22, 1988
Decision date	Mar 9, 1988
Days to decision	47 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