FDA 510(k) Premarket Notification

K032613 TEMPORARY TRANSVENOUS PACEMAKER PLACEMENT ASSIST DEVICE

CLEARED

Nov 20, 2003
87 days to decision

K032613 · Product code: **LDF** · Cardiovascular
Source: https://www.510kdatabase.net/k032613/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Aug 25, 2003
Decision date	Nov 20, 2003
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Peter M. Rothenberg, M.D.**
Location	San Clemente, CA, US
Contact	PETER M ROTHENBERG
510(k) history	1 submissions · 1 cleared · 2003-2003