FDA 510(k) Premarket Notification

K011980 ADAPTER, PACING ANALYZER/UNIVERSAL PACING ADAPTER, MODELS 4820 AND 4825

CLEARED

Sep 12, 2001
79 days to decision

K011980 · Product code: **DTE** · Cardiovascular
Source: https://www.510kdatabase.net/k011980/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Jun 25, 2001
Decision date	Sep 12, 2001
Days to decision	79 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Pace Medical**
Location	Waltham, MA, US
Contact	ROBERT C MACE
510(k) history	19 submissions · 19 cleared · 1987-2001