

**K011980 ADAPTER, PACING ANALYZER/UNIVERSAL PACING
ADAPTER, MODELS 4820 AND 4825**Sep 12, 2001
79 days to decisionK011980 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011980/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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