

K970497 PACE 101HJun 4, 1997
114 days to decisionK970497 · Product code: **DTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k970497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Feb 10, 1997
Decision date	Jun 4, 1997
Days to decision	114 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sulzer Oscor, Inc.
Location	Palm Harbor, FL, US
Contact	MILA DOSKOCIL
510(k) history	2 submissions · 1 cleared · 1997-1999

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