

K033130 PACE 101/PACE 101H, MODEL 3077 SSI TEMPORARY PULSE GENERATOROct 31, 2003
31 days to decisionK033130 · Product code: **DTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k033130/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Sep 30, 2003
Decision date	Oct 31, 2003
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osyka Medical, Inc.
Location	La Jolla, CA, US
Contact	MARKUS J OSYPKA
510(k) history	7 submissions · 6 cleared · 2002-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033130/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026