

**K882391 OPUS 3 PULSE GENERATORS MODELS
4003,4004,4023,4024**Nov 14, 1988
157 days to decisionK882391 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k882391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 10, 1988
Decision date	Nov 14, 1988
Days to decision	157 days
Third-party review	No

APPLICANT

Company	Ela Medical, Inc.
Location	Mchenry, IL, US
Contact	TOM S ANDERSON
510(k) history	43 submissions · 36 cleared · 1979-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k882391/> 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 July 3, 2026