

**K882427 CARDIAC PACE. OPUS 4000 MODELS  
4043/4044/4063/4066**Sep 23, 1988  
102 days to decisionK882427 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k882427/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 13, 1988
Decision date	Sep 23, 1988
Days to decision	102 days
Third-party review	No

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k882427/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 3, 2026