

**K900461 OPUS MODEL 4021, VVI, 5MM UNIPOLAR**Mar 14, 1990  
42 days to decisionK900461 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k900461/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 31, 1990
Decision date	Mar 14, 1990
Days to decision	42 days
Third-party review	No

**APPLICANT**

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Company	<b>Ela Medical, Inc.</b>
Location	Mchenry, IL, US
Contact	PAUL KOHL
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/k900461/>, 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