

**K897116 OPTIMA MPT MODEL 5281E AND MODEL 5282E**Mar 14, 1990  
78 days to decisionK897116 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k897116/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Dec 26, 1989
Decision date	Mar 14, 1990
Days to decision	78 days
Third-party review	No

**APPLICANT**

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Company	<b>Telectronics Pacing Systems, Inc.</b>
Location	Englewood, CO, US
Contact	DUANE A SCHULTZ
510(k) history	20 submissions · 18 cleared · 1989-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k897116/>; 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 5, 2026