

**K853425 CARIO-PACE DURAPULSE P101 COATED PULSE GENERATOR**Aug 19, 1985  
5 days to decisionK853425 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k853425/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Aug 14, 1985
Decision date	Aug 19, 1985
Days to decision	5 days
Third-party review	No

**APPLICANT**

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Company	<b>Cardio-Pace Medical, Inc.</b>
Location	St. Paul, MN, US
Contact	RONALD J GMYREK
510(k) history	3 submissions · 3 cleared · 1985-1987

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853425/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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