

**K854919 BIPOLAR CARDIAC PULSE GENERATOR WITH  
TELEMETRY**Dec 19, 1985  
10 days to decisionK854919 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k854919/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Dec 9, 1985
Decision date	Dec 19, 1985
Days to decision	10 days
Third-party review	No

**APPLICANT**

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Company	<b>Cook Pacemaker Corp.</b>
Location	Mchenry, IL, US
Contact	RICHARD W SHIRLEY
510(k) history	34 submissions · 31 cleared · 1981-1997

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854919/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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