

**K780238 PACEMAKER, PROLITH 23U. PULSE GENERATOR**Mar 15, 1978  
30 days to decisionK780238 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k780238/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 13, 1978
Decision date	Mar 15, 1978
Days to decision	30 days
Third-party review	No

**APPLICANT**

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Company	<b>Edwards Pacemaker Systems</b>
Location	Mchenry, IL, US
510(k) history	13 submissions · 13 cleared · 1977-1979

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k780238/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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