

**K844841 KALOS-04 PULSE GENERATOR**Apr 18, 1985  
127 days to decisionK844841 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k844841/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Dec 12, 1984
Decision date	Apr 18, 1985
Days to decision	127 days
Third-party review	No

**APPLICANT**

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Company	<b>Biotronik Sales, Inc.</b>
Location	Mchenry, IL, US
Contact	CAWTHON
510(k) history	41 submissions · 41 cleared · 1980-1988

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k844841/>, 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 7, 2026