

**K894240 NEOS 02**Oct 26, 1989  
128 days to decisionK894240 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k894240/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 20, 1989
Decision date	Oct 26, 1989
Days to decision	128 days
Third-party review	No

**APPLICANT**

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Company	<b>Biotronik Cardiac Pacemakers</b>
Location	Lake Oswego, CA, US
Contact	RICHARD STOUT
510(k) history	3 submissions · 3 cleared · 1989-1990

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894240/>, 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 6, 2026