

**K914109 PIKOS 01 & PIKOS E 01**Feb 26, 1992  
166 days to decisionK914109 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k914109/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Sep 13, 1991
Decision date	Feb 26, 1992
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biotronik, GmbH &amp; Co.</b>
Location	Lake Oswego, OR, US
Contact	KEN M RATHNOW
510(k) history	18 submissions · 17 cleared · 1989-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k914109/> 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 4, 2026