

**K952328 NANOS, PIKOS 01/E01, 01-A, E01-B, LP 01/LP E01**Sep 29, 1995  
134 days to decisionK952328 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k952328/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	May 18, 1995
Decision date	Sep 29, 1995
Days to decision	134 days
Third-party review	No

**APPLICANT**

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Company	<b>Biotronik, Inc.</b>
Location	Lake Oswego, OR, US
Contact	LAUREN L FOOTE CHRISTENSEN
Website	<a href="https://www.biotronik.com">https://www.biotronik.com</a>
510(k) history	85 submissions · 67 cleared · 1994-2026

Biotronik, Inc. designs and manufactures advanced active implants for cardiac rhythm management, monitoring, and electrophysiology. The company operates with a manufacturing facility in Lake Oswego, Oregon, and serves patients globally through innovative cardiovascular solutions. Biotronik has received FDA 510(k) clearances from total submissions since its first clearance in 1994. The company specializes exclusively in cardiovascular devices, including pacing systems, implantable cardioverter defibrillators, cardiac resynchronization therapies, and electrophysiology cathe...

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