

**K833104 BIOTRONIK D2K UNIPOLAR PE-60/4**Oct 19, 1983  
37 days to decisionK833104 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k833104/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Sep 12, 1983
Decision date	Oct 19, 1983
Days to decision	37 days
Third-party review	No

**APPLICANT**

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Company	<b>Biotronik Sales, Inc.</b>
Location	Mchenry, IL, US
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/k833104/>; 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