

**K802294 POLY FLEX IMPLANTABLE PACING LEAD**Apr 3, 1985  
1657 days to decisionK802294 · Product code: **DTB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k802294/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Sep 19, 1980
Decision date	Apr 3, 1985
Days to decision	1657 days
Third-party review	No

**APPLICANT**

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Company	<b>Intermedics, Inc.</b>
Location	Mchenry, IL, US
510(k) history	211 submissions · 201 cleared · 1977-1996

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k802294/> 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 May 28, 2026