

**K812989 INTERMEDICS POLYFLEX-MODEL 493-03 LEAD**Nov 16, 1981  
21 days to decisionK812989 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k812989/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Oct 26, 1981
Decision date	Nov 16, 1981
Days to decision	21 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/k812989/> 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