

K812991 INTERMEDICS POLYFLEX-MODEL 483-04 LEADNov 16, 1981
21 days to decisionK812991 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k812991/>**SUBMISSION DETAILS**

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

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

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Device record: <https://www.510kdatabase.net/k812991/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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