

K813028 POLY-FLEX PACING LEADSDec 10, 1981
43 days to decisionK813028 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k813028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Oct 28, 1981
Decision date	Dec 10, 1981
Days to decision	43 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/k813028/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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