

K802295 POLY FLEX IMPLANTABLE PACING LEADFeb 9, 1981
143 days to decisionK802295 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k802295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Sep 19, 1980
Decision date	Feb 9, 1981
Days to decision	143 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k802295/> Data sourced from FDA 510(k) public records (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. - Generated May 28, 2026