

**K864564 MODEL 486-05 POLYFLEX(R) IMPLANTABLE PACING
LEAD**Dec 5, 1986
16 days to decisionK864564 · Product code: **DTB** · Cardiovascular
Source: <https://www.510kdatabase.net/k864564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Nov 19, 1986
Decision date	Dec 5, 1986
Days to decision	16 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864564/> 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