

**K864002 MODEL 431-06 POLYFLEX IMPLANTABLE PACING  
LEAD**Nov 20, 1986  
37 days to decisionK864002 · Product code: **DTB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k864002/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Oct 14, 1986
Decision date	Nov 20, 1986
Days to decision	37 days
Third-party review	No

**APPLICANT**

---

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

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864002/> 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