

**K883016 POLYSAFE IMPLANT. PACING LEADS W/TINED FIXA.  
TIP**Sep 16, 1988  
59 days to decisionK883016 · Product code: **DTB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k883016/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Jul 19, 1988
Decision date	Sep 16, 1988
Days to decision	59 days
Third-party review	No

**APPLICANT**

---

Company	<b>Cardiac Control Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	Scott J Mindrebo
510(k) history	26 submissions · 24 cleared · 1983-1997

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k883016/> 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 July 4, 2026