

**K844857 PACESETTER SYSTEMS, INC. ENDOCARDIAL SCREW-  
IN LEAD**Feb 14, 1985  
62 days to decisionK844857 · Product code: **DTD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k844857/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker Lead Adaptor (DTD)
Date received	Dec 14, 1984
Decision date	Feb 14, 1985
Days to decision	62 days
Third-party review	No

**APPLICANT**

---

Company	<b>Pacesetter Systems</b>
Location	McHenry, IL, US
Contact	NESTOR KUSNIERZ
510(k) history	96 submissions · 96 cleared · 1976-1991

Pacesetter Systems was a biotechnology company founded by Alfred E. Mann in 1965, headquartered in McHenry, US. The company pioneered implantable medical devices, including the first commercial rechargeable implantable pacemaker and early telemetry-enabled systems. Pacesetter Systems received FDA 510(k) clearances from total submissions between 1976 and 1991. The company's regulatory focus centered on Cardiovascular devices, which represented 91% of all submissions. This historical record reflects the company's core expertise in pacemaker technology, leads, adapters, and ...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k844857/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 30, 2026