

**K801455 LEAD, ENDOCARDIAL, TINED, BIPOLAR, 5MM**Oct 23, 1980  
121 days to decisionK801455 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k801455/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Jun 24, 1980
Decision date	Oct 23, 1980
Days to decision	121 days
Third-party review	No

**APPLICANT**

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Company	<b>Pacesetter Systems</b>
Location	Mchenry, IL, US
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 ...