

**K833647 PACEMAKER SYS ANALYZER #384**Dec 16, 1983  
60 days to decisionK833647 · Product code: **KRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k833647/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function, Indirect (KRE)
Date received	Oct 17, 1983
Decision date	Dec 16, 1983
Days to decision	60 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 ...