

**K831443 PACELINE PATIENT TRANSMITTER MODEL 324**Aug 12, 1983  
99 days to decisionK831443 · Product code: **DXH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k831443/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	May 5, 1983
Decision date	Aug 12, 1983
Days to decision	99 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 ...

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Device record: <https://www.510kdatabase.net/k831443/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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