

K813150 DIRECTIONAL BOOTDec 2, 1981
26 days to decisionK813150 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k813150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Nov 6, 1981
Decision date	Dec 2, 1981
Days to decision	26 days
Third-party review	No

APPLICANT

Company	Pacesetter Systems
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/k813150/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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