

**K861440 LEADS UTILIZ VOLUN STAND #1 3.2 MM
UNI/BIOPOLAR CO**May 13, 1986
26 days to decisionK861440 · Product code: **DTB** · Cardiovascular
Source: <https://www.510kdatabase.net/k861440/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Apr 17, 1986
Decision date	May 13, 1986
Days to decision	26 days
Third-party review	No

APPLICANT

Company	Pacesetter Systems
Location	Mchenry, IL, US
Contact	RITA BROWN
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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